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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61F 2/06, A61L 27/00, A61M 29/02

A1

(11) International Publication Number: **WO 98/40034**

(43) International Publication Date: 17 September 1998 (17.09.98)

(21) International Application Number: PCT/US98/04792

(22) International Filing Date: 12 March 1998 (12.03.98)

(30) Priority Data:

08/815,096	12 March 1997 (12.03.97)	US
08/857,323	16 May 1997 (16.05.97)	US
08/982,247	1 December 1997 (01.12.97)	US
08/982,246	1 December 1997 (01.12.97)	US
08/982,120	1 December 1997 (01.12.97)	US
08/984,481	1 December 1997 (01.12.97)	US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications

US	08/815,096 (CIP)
Filed on	12 March 1997 (12.03.97)
US	08/857,323 (CIP)
Filed on	16 May 1997 (16.05.97)
US	08/982,247 (CIP)
Filed on	1 December 1997 (01.12.97)
US	08/982,246 (CIP)
Filed on	1 December 1997 (01.12.97)
US	08/982,120 (CIP)
Filed on	1 December 1997 (01.12.97)
US	08/984,481 (CIP)
Filed on	1 December 1997 (01.12.97)

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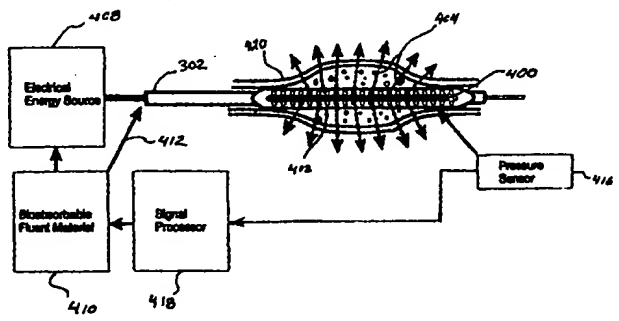
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: A RADIOPAQUE, BIORESORBABLE STENT, CREATED IN SITU



(57) Abstract

A stent is created *in situ* at a stenosed site in a blood vessel from a flowable material which is delivered in a porous, flexible angioplasty balloon. The flowable material is extruded in place into a mold cavity formed by the porous surface of the angioplasty balloon and the surrounding endovascular wall. The flowable material can include a radiopaque marker and is capable of changing phase to a solid upon the application of energy above a predetermined threshold. When the flowable material has been extruded into the mold cavity, energy is applied to solidify the material and to interlink the stent material with fissures and breaks in the endovascular wall. The balloon is then withdrawn leaving a fully formed stent having a central lumen for enhanced blood flow. Including a radiopaque stent material in the stent allows for direct fluoroscopic visualization for enhanced control over the positioning and formation of the stent. A radiopaque stent also provides the advantage of enhanced long term observation of the stent.

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A RADIOPAQUE, BIORESORBABLE STENT, CREATED *IN SITU*

BACKGROUND

Field of the Invention

The field of the present invention relates generally to an endovascular stent. In particular, the field of the invention relates to stents created *in situ* in a blood vessel from a radiopaque fluent bioresorbable material. The stent is cast in the blood vessel from a mold and cured to form a smooth surface which prevents entrapment of thrombogenic material and minimizes the risk of restenosis.

Angioplasty is a procedure for treating blood vessels or arteries which have become narrowed by plaque deposits. Typically, a catheter comprising an inflatable balloon is advanced along a path of travel through the artery to a narrowed or stenosed region. The balloon is inflated at the stenosed region of the artery causing it to be expanded. The balloon is then withdrawn.

The effect of inflating a balloon against a narrowed arterial wall typically produces injuries. When the angioplasty balloon is inflated, the single layer of cells constituting the endothelial lining typically are torn away. Also, the inflation of the balloon may induce fissures or other injuries to the arterial wall. The loss of endothelial cells and injury to the arterial wall create an irregular surface. Such tears and nonconformities in the vessel wall, along with the loss of the endothelial layer, expose the wall of the blood vessel which will activate the coagulation system. This in turn may form sites for promoting the growth of blood clots, which occlude and narrow the artery. Bioresorbable materials can be biodegraded *in vivo* and subsequently absorbed into the living tissue through cellular metabolic pathways.

Conventional cardiology procedures include the introduction of a stent to a target site in a blood vessel after balloon angioplasty has been performed. Conventional stents typically are fabricated of metal or plastic and comprise a central lumen to permit the flow of blood through the vessel. The metal or plastic composition is necessary to provide sufficient rigidity to hold the artery open.

A conventional stent remains in the blood vessel indefinitely, and may have adverse, long-term effects. The endothelial lining of a blood vessel normally comprises a single layer of cells. This layer of cells covers the internal surface of all vessels and renders that surface compatible, that is non-thrombogenic and non-reactive, with blood. When a conventional stent is introduced into an artery, the endothelial cells may be torn away. The loss of the endothelial layer and tearing within the luminal wall may generate a surface which is thrombogenic, that is likely to induce clotting and cell growth.

A conventional stent is fabricated outside of the body and introduced into the blood vessel. The stent is then advanced along a path of travel to the point of intervention. The inherent stiffness and pre-formed configuration of the stent often results in trauma to the vessel wall and endothelial lining as the stent is advanced through a blood vessel.

A conventional stent has a fixed range of expansion within a blood vessel and ultimately may not be adapted to the particular configuration of the blood vessel at the intervention site. For example, an expandable stent may be delivered to the target site in a compressed form. The stent is then expanded to its predetermined configuration once it reaches the target site. However, because the stent has been fabricated outside of the body and caused to assume a predetermined configuration, the stent ultimately may prove to be too small in diameter, even after expansion. Such a stent may be too small to remain in place, cannot be affixed properly to the vessel wall, and may even move and create an impediment to blood flow. In that case, such a stent may comprise a life threatening situation and would have to be removed surgically.

A further disadvantage of a conventional stent is that after insertion at a target site, the stent may be expanded to such a diameter that the blood vessel is injured or torn. Thus, a conventional stent may continue to pose problems of bio-incompatibility, injury to the blood vessel, proliferation of cells and may exacerbate a thrombogenic condition.

A conventional stent also suffers from disadvantages related to accurate positioning within a blood vessel. Due to the inability to observe the stent

directly as it is advanced toward a stenosed region of a blood vessel, it is extremely difficult to achieve accurate positioning of a stent. In addition, an established stent may undergo a shift in position, away from the stenosed area. This may result in blockage of the blood vessel which necessitates immediate medical intervention.

A conventional approach to overcoming the foregoing problems associated with a rigid, expandable stent is provided by U.S. Patent No. 5,100,429, which is incorporated herein in its entirety by this reference. U.S. Patent No. 5,100,429 provides an endovascular stent comprised of a sheet of biologically compatible material rolled onto an outer surface of an inflatable balloon to form a tubular body. The outer portion of the tubular body comprises a cross-linkable adhesive material. When the balloon is inflated, the adhesive material on the outside surface of the tubular body attaches to the walls of the blood vessel. Laser energy preferably is applied from within the balloon in a wave-length range required to effect cross-linking of the adhesive material on the surface of the tubular body of the stent.

The endovascular stent and delivery system as taught by U.S. Patent No. 5,100,429 has disadvantages. The stent exposes vessel walls to trauma and potential loss of the single layer of cells constituting the endothelial lining as the stent is advanced along a path of travel in the blood vessel. The need to advance the rolled stent positioned around the outside of the angioplasty balloon may inadvertently introduce highly thrombogenic materials such as proteins into lesions, fissures or other traumatized areas on the vessel walls which lie in the path of travel of the stent.

Further, the need to advance the stent along the path of travel to the intervention site causes the surface of the stent to be contaminated with thrombogenic material as it moves along the blood vessel as previously described. This may degrade the cross-linkable adhesive which covers the outer surface of the stent. This in turn may result in incomplete adhesion of the stent to the arterial wall and may result in significant problems if the stent fails to adhere properly or loosens and moves out of position.

Also, it is known that when an angioplasty balloon is inflated, the endothelial cells will be torn away from the vessel walls. In order to position the endovascular stent, the angioplasty balloon must be inflated to a diameter greater than that of the blood vessel or artery in order to compress the surface of the stent against the vessel wall. This damages endothelial cells and introduces trauma as well as highly thrombogenic materials at the target site. New clots may form, thus defeating the purpose of a conventional endovascular stent and delivery system.

Another conventional method for treating an arterial wall which has been injured during an angioplasty procedure is provided by U.S. Patent No. 5,092,841. In order to overcome the problem of thrombogenic, inflammatory, or proliferative adverse reactions which normally occur after angioplasty, the '841 patent teaches a method for coating a luminal surface with an insoluble, permanent or semi-permanent bio-protective material. An angioplasty catheter is positioned adjacent to the lesion being treated. A bio-protective material is delivered between the arterial wall and the angioplasty catheter. During apposition of the angioplasty catheter to the arterial wall, the layer of bio-protective material is entrapped between the balloon and the wall. Due to capillary action and pressure exerted radially outward by the balloon, the bio-protective material enters and permeates the vessels of the arterial wall as well as the fissures and dissected planes of the tissue. Thermal energy also may be applied to the lesion to bond the bio-protective material to the arterial wall using laser balloon angioplasty (LBA). The insoluble layer of material bonds chemically or is thermally cross-linked to tissues on the luminal surface.

This technique has disadvantages in that the heat necessary to bond or cross-link the material to the tissue company arterial wall necessarily causes trauma. In addition, the insoluble, bioprotective material remains permanently in the artery. If the material should become dislocated or otherwise move out of position, severe problems may result. In the event the material must be removed or repositioned, such repositioning likely could not be done without completely

destroying the artery due to the nature of permanent cross-linking of the insoluble material.

Endovascular tissues are known to be porous or can have fissures, particularly tissues which have been injured by an angioplasty operation. Such delicate tissues may be even further damaged by a conventional stent which must be positioned by the expansion of a catheter balloon and adhered to the tissues by the application of thermal energy to such an extent as to cause cross-linking. The resulting trauma to the endovascular lumen can be severe. Also, the permanent placement of a stent can forever prevent endovascular tissue from repairing itself. Instead, the tissue would tend to grow around the stent.

Accordingly, there is a need for a stent which can be delivered and positioned with a minimum of trauma to tissue which has already been damaged by angioplasty. It would be desirable if the stent could be delivered in a fluent state so as to minimize the risk of any trauma whatsoever to the tissue. Once delivered, it is preferable to provide a stent which could be reabsorbed by endovascular tissue, thus promoting the healing of tissue in place.

There is a need for providing a new type of stent which can be introduced to a target site in an artery substantially without trauma and without contaminating the target site or any lesion with thrombogenic material which would cause restenosis. There is also a need for an improved stent which once placed in the artery can prevent restenosis and at the same time not create a permanent danger to the patient in the event the stent is dislodged.

What is also needed is a stent and a method for delivering the stent which can be considerably downsized over what is presently available and which can be delivered to a target site without injury to the delicate, single layer of cells constituting the endothelial lining following an angioplasty.

It also would be desirable to provide a component in the fluent composition of the stent in order to render both the fluent form of the stent material and the subsequently formed stent to be radiopaque. This would enable the fluent stent material to be introduced in a blood vessel under direct fluoro-visualization in real time. This would enable an extremely accurate positioning

of the stent at the stenosed region of a blood vessel and thus would ensure a very high level of safety for the patient.

In addition, the introduction of a radiopaque fluent stent material would enable a physician to directly visualize how the fluent stent material is being distributed against the vascular wall through the microporous membrane. This would obviate the need for adaptive feedback control for the delivery of the fluent stent material and would significantly decrease the cost of the procedure. Also, direct visualization of a radiopaque stent material would enable greater control and readjustment of the position of the stent inside the blood vessel in the event of any uneven distribution of fluent stent material through the microporous membrane. Such a radiopaque fluent stent material would thereby help to achieve an extremely high probability of success in this treatment procedure.

It also would be desirable to use a radiopaque fluent stent material so that the extraction of the microporous membrane or an angioplasty balloon may be visualized directly. Such a radiopaque stent material would enable the physician to determine whether the newly formed stent has been damaged or changed its position and/or shape during extraction of the delivery vehicle, such as an angioplasty balloon, or the like.

The use of a radiopaque fluent stent material would allow direct visualization of the extrusion of the fluent stent material from a microporous membrane. This advantageously would prevent excess fluent stent material from being extruded into the blood vessel.

SUMMARY

In order to overcome the foregoing disadvantages of a conventional endovascular stent and delivery system, an aspect of the present invention provides a bioresorbable stent that is created *in situ* and in living tissue. Another aspect of the present invention provides a radiopaque bioresorbable stent that is created *in situ* and in living tissue.

The stent is created at the site of intervention in a stenosed region of a blood vessel from a bioresorbable material capable of undergoing a microstructural transformation and phase transition from a fluent form to a solid state upon the application of heat or optical energy at a predetermined threshold. The bioresorbable stent material interlinks with fissures and breaks in living tissue. The stent material in its fluent state also can interpenetrate pores of living tissue and can repair an endovascular luminal surface.

Another aspect of the invention comprises the addition of a component in the fluent stent material to render both the fluent form and the subsequent non-fluent form of the material, in the stent, to be radiopaque.

The fluent stent material can be formulated from any material which is suitable as a photoforming material. An example of such a material is a photo-sensitive pre-polymer which is capable of effecting a change of state from a fluent material to a solid when irradiated with a suitable source of ultraviolet light at a predetermined intensity level. The threshold of optical intensity as well as the threshold energy input necessary to effect a change of state is referred to generally as the activation threshold.

A radiopaque material is added to the fluent stent material to render both the fluent form and the final stent radiopaque. Examples of such radiopaque components are: barium sulfate, heavy dense metals such as gold, or MD-60, and organically bound iodine such as that made by MALLINCKRODT. Any other radiopaque marker approved for intravascular use also may be employed.

A porous angioplasty balloon, porous catheter tube or similar containment vessel having a porous surface delivers the stent material to the target site in a fluent or flowable state. Since the stent material is in a fluent form encased within the angioplasty balloon, it is protected against contamination from thrombogenic material as it is advanced along a blood vessel. Also, the flexible, pliant nature of the angioplasty balloon and the fluent stent material minimizes the coefficient of friction and minimizes or substantially eliminates trauma to the vessel wall. Once at the site of intervention, the fluent

stent material is forced outward through the pores of the balloon through the application of pressure or by thermal expansion.

Using the expandable balloon as a mold surface, the fluent bioresorbable material is cast in a mold cavity or annular space defined by the surface of the balloon and the surrounding endovascular wall. After the fluent material has been ejected from the balloon, cast in the mold, and interpenetrated fissures in the injured endovascular surface of the blood vessel, the stent material is optically initiated or is heated to its phase activation threshold at which point the fluent stent material undergoes a phase change to its solid state.

The angioplasty balloon is then withdrawn from the solidified stent material, leaving a smooth central passageway through the stent for providing enhanced blood flow. The solidified stent is sufficiently rigid to be capable of holding the artery or blood vessel in a correct configuration until the stent material is gradually reabsorbed into the vascular wall. In this way, the artery or blood vessel heals itself and regains its proper function. In another aspect of the invention, a radiopaque marker (barium sulfate, dense metals such as gold, organically bound iodine or equivalent radiopaque component) may be provided on the surface of the microporous membrane or angioplasty balloon in accordance with techniques which are well known. This advantageously would enable the physician to observe the withdrawal of the angioplasty balloon in real time and thereby exert greater control over the removal of the angioplasty balloon.

According to a further aspect of the invention an annular space between surface of the expandable porous balloon and the surrounding surface of the endovascular wall creates a mold cavity suitable for reaction injection molding of a stent at the intervention site. Two or more reactive fluid stent components are injected simultaneously or sequentially into the mold through the porous surface of the balloon resulting in impingement mixing and polymerization.

In another embodiment, a bioresorbable filler material is provided in filament, fiber or woven form. In a preferred case, the bioresorbable filler comprises suture like threads woven into a loose network structure having a

comprises suture like threads woven into a loose network structure having a substantially cylindrical shape. In this collapsed form, the woven network structure is draped and loosely adhered around a catheter balloon having a porous surface, and is introduced to an aneurysm site in a blood vessel or the like in the standard manner. The balloon contains a quantity of fluent matrix material.

The filler material can be radiopaque. The radiopaque marker may comprise barium sulfate, a dense metal such as gold, a material such as organically bound iodine, or any equivalent radiopaque material. The fluent matrix material may or may not be radiopaque.

Once at a site for treatment, the balloon is expanded by the application of pressure. This also expands the woven network of bioresorbable filler positioned around the balloon to the vicinity of the vessel wall. The fluent matrix material is then extruded from the pores in the surface of the balloon in the same fashion as previously described. As the fluent matrix material engulfs the expanded network of filler material, energy is applied to effect a change of phase to provide a solidified stent which is cast in place against the surface of the angioplasty balloon and the surrounding vessel wall as previously described.

This provides the advantage of a bioresorbable, fiber net reinforced stent which is resistant to radial expansion yet still has a smooth surface due to the adjacent smooth surface of the balloon against which the stent is cast. The problems often encountered from the contact of sutures with flowing blood, for example thrombosis, cell deposition and the like would be obviated because the fibers are safely sealed into the bulk of the stent matrix. This embodiment provides an additional advantage wherein the pliant net of bioresorbable filler material in collapsed form causes minimal trauma to the vessel intima surface during insertion and transport to the aneurysm site.

In another aspect, the extruded fluent, bioresorbable stent matrix material not only engulfs the fiber net of filler material, but also inter-penetrates fissures in the vascular wall. As pressure forces the fluent stent material out of

just above the activation threshold to the stent material, this effects a change of state whereby the outer portion of the stent material is locked in place by interpenetration of the fissures. At the same time the stent material adjacent the balloon surface is solidified to create a substantially solid, smooth surface over the vascular wall.

In an aspect of the invention, the addition of a radiopaque component to the fluent stent material enables the fluent stent material to be introduced under direct fluoro-visualization in real time. This enables the physician to directly visualize how the fluent stent material is being distributed against the endovascular wall through the microporous membrane of the angioplasty balloon. After the fluent stent material has solidified, the extraction of the deflated angioplasty balloon can be directly visualized. It will be appreciated that the addition of the radiopaque component eliminates the need for adaptive feedback to precisely control the amount of fluent stent material being extruded through the microporous membrane.

Alternatively, smoothness and thickness control may be provided by an active feedback control system. A microelectronic pressure sensor is disposed within the balloon for adaptive feedback control of the amount of fluent stent material to be passed through the pores of the balloon. The adaptive feedback control helps to ensure that the fluent stent material is evenly distributed as it is cast against the endovascular wall. Known feedback methods are then used to control the amount of fluent stent material flowing through the pores of the balloon.

In another aspect of the invention, the stent is bioresorbable and is gradually absorbed by the living tissue. In this way, the stent is able to hold the injured blood vessel in place until the vessel essentially heals itself. The creation of the stent by the process of casting in a mold cavity created by the surface of an angioplasty balloon and surrounding vascular wall provides a smooth coating of stent material over the endovascular wall and also provides a smooth central passageway for the flow of blood when the balloon is removed from the vessel. The smooth surface of the balloon, acting as a mold for the stent material,

substantially eliminates unconformities in the endovascular wall which would lead to the entrapment of thrombogenic material. The substantially smooth surface formed by the casting of the stent in place at the site of intervention also enhances blood flow and reduces thrombogenic conditions which lead to restenosis.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other advantages of the present invention may be appreciated from studying the following detailed description of the invention together with the drawings in which:

Figure 1A is a cross-sectional view showing a first system for advancing a porous balloon containing a quantity of fluent stent material along a path of travel in a blood vessel, or the like.

Figure 1B shows an alternate system for steering a porous catheter balloon containing a quantity of fluent stent material along a path of travel in a blood vessel or the like.

Figure 2A is a cross-sectional view of a porous angioplasty balloon containing fluent stent material inserted in a blood vessel and advanced to an aneurysm site according to an aspect of the present invention.

Figure 2B is a cross-sectional view of the process of expelling the fluent stent material from the porous angioplasty balloon surface according to an aspect of the present invention.

Figure 2C is a cross-sectional view showing the casting of the stent material in a mold formed by the surface of the balloon and the surrounding endovascular wall, and the application of energy to solidify the cast material into a stent according to an aspect of the present invention.

Figure 2D is a cross-sectional view showing the finalized molded stent and withdrawal of the catheter balloon.

Figure 3A shows an alternate procedure for delivering a stent material to build a stent in place for repairing a dissected or damaged blood vessel wall.

Figure 3B shows deposition of fluent stent material from the porous surface of the balloon to interpenetrate dissected tissue and fissures in the endovascular wall.

Figure 3C shows the application of energy to set the stent material by effecting a change of state of the bioresorbable stent material from a fluent state to a solid state.

Figure 3D shows the withdrawal of the balloon, the finalized molded stent and repair of the dissected vessel wall in accordance with an aspect of the present invention.

Figure 4A shows a cross-sectional view of a microporous catheter balloon covered by a cylindrical network of a bioresorbable filler material in filament or woven form.

Figure 4B shows the expansion of the catheter balloon and surrounding bioresorbable filler material and the extrusion of fluent material from the microporous membrane into the expanded bioresorbable stent material.

Figure 4C is a cross-sectional view showing the application of energy to set the stent material.

Figure 4D shows the final molded stent with embedded bioresorbable filler material and withdrawal of the catheter.

Figure 5A is a schematic view showing a first system for applying energy to the extruded fluent stent material to effect a change of state to a solid.

Figure 5B is a schematic diagram showing an alternate system for applying energy to set the stent material.

Figure 5C is a schematic diagram showing an alternative system for applying energy to set the stent material.

Figure 6 is schematic diagram for a typical system for adaptive feedback and automated control of a method for applying energy to set the stent material.

Figure 7A is a cross-sectional view showing an example of a porous surface of a containment vessel such as a balloon catheter configured to create a mold cavity for forming a stent with a desired geometry.

Figure 7B shows an example of a custom shaped stent, created *in situ*, having a geometric shape formed by the mold surface shown in Figure 7A.

DESCRIPTION

Figures 1A and 1B show two alternate systems for advancing a porous angioplasty balloon and catheter to a stenosed or injured site in a blood vessel, artery, or the like for building a stent *in situ*.

In Figure 1A a guidewire system is shown for advancing a porous angioplasty balloon 100 along a path of travel in a typical blood vessel 103. A guidewire 102 is attached to an end of angioplasty balloon 100. The other end of angioplasty balloon 100 is attached to a hollow catheter tube 108 for the introduction of a fluent stent material into angioplasty balloon 100 as will be explained. The guidewire 102 is adapted to provide a path of travel within the artery or blood vessel 103 along which the angioplasty balloon 100 can be advanced.

Figure 1B shows an alternate steerable system in which a porous balloon 100 is advanced along a path of travel through blood vessel 103. The porous angioplasty balloon 100 is attached to a steerable catheter tube 105. The steerable catheter tube 105 comprises a distal end with a steering element 107. The other end of catheter tube 105 is connected to a source of fluent stent material for delivery to the porous balloon 100 in accordance with techniques which are well known. In this system, the balloon 100 is advanced along a path of travel in a blood vessel by pressure applied to steerable catheter tube 105. A steering element 107 can be a shape memory alloy activated device or other conventional steering device which enables the application of torque for steering balloon 100 in a particular direction when a junction is reached.

Referring to Figures 2A-2D, a stent is formed *in situ* from a flowable bioresorbable material contained in a porous angioplasty balloon 100. The purpose of the stent is to hold open a narrowed or stenosed vessel. In accordance with an aspect of the invention, a stent is created by casting against a

mold formed by the surface of porous balloon 100 and the surface of the surrounding endovascular wall 106 of the blood vessel 104 as will be explained. That is, the stent is created *in situ*, at the site of intervention. It will be appreciated that this eliminates the need to advance a rigid stent along a path of travel in an artery or blood vessel. In accordance with an aspect of the present invention, the material for forming a stent is transported to the site of medical intervention in a fluent form to minimize or substantially eliminate trauma to delicate endovascular tissue. This substantially reduces trauma to the single cell endothelial lining of the endovascular wall.

In accordance with this aspect of the invention, a stent material is delivered through a blood vessel in a fluent form, contained by an angioplasty balloon 100 comprising a porous micromembrane. A stent is formed inside the blood vessel at the site of a stenosed area or other injury requiring medical intervention to hold the blood vessel open to permit the free passage of blood.

Referring to Figures 2A-2D, a catheter comprising generally a hollow tube 108 has a central lumen for the delivery of a flowable bioresorbable material for making the stent. A first end of the catheter tube 108 is attached to a supply of the bioresorbable stent material in a fluent or flowable form (not shown). A distal end of the catheter is attached to a porous angioplasty balloon 100 as shown.

In accordance with an aspect of the invention, a radiopaque marker can be included on the microporous membrane surface of the angioplasty balloon 100. The radiopaque marker can be a radiopaque dye or can comprise a thin surface of a dense metal such as gold which is provided over the surface of the angioplasty balloon by well known techniques such as chemical vapor deposition (CVD), electroplating or other equivalent process. The use of a radiopaque dye on the microporous membrane surface of the angioplasty balloon 100 provides greatly increased control and flexibility in stent positioning and formation. The radiopaque dye makes possible a direct visualization of the delivery of the stent material to the target stenosed site in a blood vessel. The direct fluoro-

visualization made possible by the radiopaque stent material also provides a very high level of accuracy and patient safety in positioning the angioplasty balloon.

Any equivalent containment vessel having a porous surface can be used in place of the porous angioplasty balloon 100. For the sake of simplicity, angioplasty balloon 100 is referred to as a porous balloon. However, angioplasty balloon 100 also may comprise a flexible, porous containment vessel such as a catheter tube which is expandable upon the application of fluid or pneumatic pressure. The important feature is that the balloon 100 or containment vessel has a flexible, porous surface which enables the fluent, bioresorbable stent material to be advanced along a path of travel in a blood vessel with minimal impact upon the endothelial lining of endovascular wall 106. The flexible porous surface also enables the fluent stent material to be expelled upon the application of pressure from within the angioplasty balloon 100 as will be explained.

The materials for suitable angioplasty balloons include, but are not limited to, membranes and materials having a plurality of pores or holes through. The materials should allow the stent material to be extruded in its fluent state upon the application of pneumatic or fluid pressure according to techniques which are well known. In an embodiment including pores, the pores are holes which are laser drilled or pin punched in the surface of an angioplasty balloon. The diameter of the holes determines the dispersion characteristics of the fluent stent material from the balloon. The pores 112 are sufficiently small to contain the stent material in a flowable or fluent state. However, the pores are configured such that upon the application of pressure to the internal volume of stent material contained within the flexible microporous membrane, the pores enable the fluent stent material to be extruded through the pores and into a cylindrical cavity or annular space 120 surrounding the expanded balloon. In one embodiment the pores can of the membrane expand to allow the fluent material to flow through the pores. While pneumatic pressure can be used to effect a radial expansion of the fluent material through the pores of the balloon surface, it is important that air does not enter the blood vessel.

The angioplasty balloon 100 is introduced to the stenosed region of the blood vessel or artery 104 in a well known manner. The porous balloon 100 comprises a flexible reservoir or vessel for containing a quantity of bioresorbable stent material in a fluent state and for delivering that material precisely where it is needed to create a stent. It will be appreciated that the minimal size of the flexible balloon 100 containing a fluent stent material also minimizes the trauma to the delicate single layer endothelial lining of the artery as the catheter is moved along a path of travel to a stenosed region or aneurysm.

In response to pneumatic or hydraulic pressure, thermal expansion, or pressure from additional fluid stent material supplied through catheter tube 108, a predetermined or closely controlled amount of the flowable, bioresorbable stent material is forced out through the pores 112 in the balloon 100 as shown by the arrows in Figure 2B, 3B and 4B.

In accordance with another aspect of the invention as shown in Figures 2A-2D, a mold cavity is formed by the annular space 120 formed between the porous membrane surface 110 of balloon 100 and the surface of the surrounding substantially cylindrical endovascular wall 106. Stated differently, the porous surface 110 of balloon 100 and the surface of endovascular wall 106 each form a mold surface against which the stent material 208 is radially extruded and cast as shown in Figures 2B-2D. A bioresorbable stent material 208 is cast against the surface 110 of the balloon 100 and is simultaneously cast conformably against the surrounding endovascular surface 106 of the blood vessel 104 as shown in Figures 2B and 2C.

A desired amount of the bioresorbable fluid is cast in place in the mold formed by the surface of the balloon and the surrounding endovascular tissue, as shown in Figure 2B. As shown in Figures 2C and 2D, energy is applied to effect a change of state of the bioresorbable stent material. That is, the bioresorbable stent material upon application of energy at an activation threshold undergoes a micro-structural transformation and changes state from a fluent material to a solid material. Bioresorbable materials capable of effecting a change of state are well known and discussed infra.

What is important is that the stent material should have a basic matrix component which is capable of effecting a change of phase from a fluent to a solid state upon the application of heat or optical energy at a predetermined activation threshold. A fluent material capable of a phase transition upon the application of optical energy at or above a predetermined threshold may be a photo initiator, photo polymer or like photoforming material. Such photoforming materials are well known to those skilled in the art.

In accordance with an aspect of the invention, a radiopaque component is provided in the fluent stent material to render both the fluent form and the subsequent non-fluent form, in the stent, radiopaque. The radiopaque component may comprise any material capable of rendering the fluent composition radiopaque. For example, the radiopaque component can comprise barium sulfate or may comprise particles of dense metals such as gold which are suspended in the fluent material. Another radiopaque component which may be added to the fluent composition to render both the fluent form and the subsequently solidified stent radiopaque is a material such as MD-60, organically bound iodine manufactured by MALLINCKRODT. Also, any equivalent radiopaque material capable of being suspended in the fluent stent material can be employed.

It will be appreciated that the radiopaque fluent stent material enables direct fluoro-visualization of the extrusion of the stent material from the angioplasty balloon. This enables direct visualization of the precise manner in which the fluent stent material becomes distributed against the endovascular wall of the blood vessel through the microporous membrane of the balloon 100. Direct visualization of the extruded radiopaque stent material 208 enables precise control and positioning of the stent material inside the vessel. This in turn achieves greater precision in forming the finalized stent. Direct visualization of the radiopaque stent material prevents an uneven fluent stent material distribution through the microporous membrane and results in greater control and uniformity of the dimensions of the final stent.

It also will be appreciated that when the fluent radiopaque stent material solidifies, the newly formed stent is likewise radiopaque and can be easily monitored over the long term using direct fluoro-visualization methods.

The process of forming a solid stent from a fluent stent material is as follows. The extrusion of the stent material from the porous balloon 100 is indicated by arrows in Figure 2B. The solidified stent material is indicated by cross hatching in Figure 2D. The fluent stent material undergoes a change of phase to a solid state upon being treated with a source of activation energy to an activation threshold. The application of energy to set and solidify the stent material is indicated by the arrows in Figure 2C. Examples of activation energy include resistive heating to a predetermined activation temperature, heating through the application of radio frequency (RF) energy at a predetermined wavelength, heating through the application of ultrasound, heating provided by an exothermic chemical reaction. Optical energy also may be applied under well know conditions which induce photo polymerization at a given threshold of intensity. Once solidified, the stent has sufficient integrity and rigidity to hold the endovascular walls in place and keep the artery open. Figure 2D shows the solidifying of the stent material.

When the stent material has sufficiently solidified, the balloon 100 is withdrawn as shown in Figure 2D. The removal of the balloon 100 creates a central lumen through the center of the finalized cylindrical stent 114 as shown in Figure 2D. The smoothness of microporous membrane 110 provides an inner mold surface against which the stent material is cast and thereby imparts a smooth surface to the central lumen 116 of the stent 114 when the balloon 100 is withdrawn. Additionally, the cast surface may be smoothed even further by pulling a heated inflated balloon surface over the casted surface in a planing process. The smooth surface of central lumen 116 advantageously enhances blood flow and prevents the formation of thrombogenic sites.

As explained previously, a radiopaque marker can be provided on the surface of the balloon 100. Any convenient technique for applying a coating of radiopaque material can be used, such as, for example, chemical vapor

deposition (CVD), electroplating, or other equivalent method for providing a coating of radiopaque material on a surface. A radiopaque surface of balloon 100 provides the advantage of real time, direct fluoro-visualization of the balloon 100. This enables both the advancement of balloon 100 and the extraction of the deflated balloon 100, after the fluent stent material has been extruded, to be directly observed and closely controlled. This also provides enhanced accuracy in positioning the stent. In addition, the radiopaque stent material enables the physician to monitor the stent to ensure that it is not damaged and that it does not change its position and/or shape during the balloon extraction. This provides a significant improvement in patient safety over conventional angioplasty techniques.

The bioresorbable stent material in its fluent state lacks sufficient mechanical integrity to form a stent. However, by delivering the bioresorbable material in a fluid form to the stenosed region of the blood vessel, trauma to the stenosed region is substantially eliminated. In addition, stenosed tissues are known to be porous or to have numerous fissures. The placement of the fluent stent material at the site of a stenosed blood vessel provides the advantage of substantially eliminating the trauma normally associated with the placement of a rigid stent. The introduction of stent material in its fluent state provides a further advantage of being able to penetrate fissures and other breaks and unconformities in injured endovascular tissue.

The process of making a , bioresorbable stent *in situ* can be used to completely repair severely damaged or dissected endovascular tissue as shown in Figures 3A-3D. The bioresorbable stent is created in place to enter penetrate fissures and breaks in endovascular tissue. In addition, the stent is gradually reabsorbed into the tissues as the blood vessel heals itself. As shown in Figure 3A, a balloon 100 comprising a microporous membrane 110 contains a quantity of fluent stent material. The balloon 100 has a distal end which is guided or advanced along a path of travel in the blood vessel to the site of a dissected, broken or injured vessel wall. The balloon 100 can be advanced along the path of travel by a guidewire 120 as shown, or by any well known method.

The other end of balloon 100 is connected to a hollow catheter tube 108. Catheter tube 108 is attached to a means for conveying either fluid or pneumatic pressure to the balloon 100. Catheter tube 108 also may provide a source of fluent stent material which can be pumped or delivered to balloon 100. The pores of the flexible microporous membrane 110 are sufficiently small to enable a quantity of bioresorbable stent material to be contained as the balloon is advanced along a path of travel in the blood vessel. However, the microporous membrane also enables the fluent stent material to be extruded from the pores upon the application of fluid or pneumatic pressure to the balloon 100 as previously explained.

As shown in Figure 3B, when pressure is applied to the fluent stent material within balloon 100, the fluent stent material is extruded through the pores of the microporous membrane 110 and is forcibly deposited into the fissures and breaks in the blood vessel by radial expansion of microporous membrane 110 as shown in Figure 3B.

The interpenetration of fissures in stenosed tissue by the fluent stent material also provides the advantage of an enhanced therapeutic effect. The flowable stent material is mixed with adjuvants to promote healing such as growth factors. Other adjuvants or therapeutically useful pharmaceutical agents can be provided in the stent material. This would include immunosuppressant agents such as cycloporin, adriamycin, and equivalents. Likewise, agents for promoting cell growth of the endothelial tissue may be incorporated in the stent material. Also, a wide variety of well known therapeutically useful pharmaceutical agents may be provided in the stent material for the prevention of restenosis. Examples of such pharmaceutical agents include anticoagulants such as heparin, anti-platelet agents, fibrinolytic and thrombolytic agents as well as anti-inflammatory agents.

It will be appreciated that the formation of a stent *in situ* from a flowable material enables heparin or other adjuvants for promoting healing to be delivered directly to the injured tissue and to interpenetrate that tissue. The therapeutic agents over time are bioreabsorbed into the surrounding tissue along with the

stent material itself. In contrast, a conventional stent is preformed outside the blood vessel and then pushed into place. Thus, there is always some trauma associated with the positioning of the stent. Further, in a conventional stent, it is not possible to deliver any therapeutic or healing agents where they are needed most, in minute fissures and breaks in the injured tissue. Additionally, it is not possible to conformably interlink a conventional preformed stent with the injured or stenosed endovascular tissue. Also, a conventional stent, formed outside of the blood vessel, cannot be conformably adapted to the unique characteristics or unique configuration of the particular site in the endovascular wall where the stent is to be located.

In accordance with an aspect of the invention, the stent is formed in two stages. In the first stage, the flowable material interpenetrates fissures and injured tissue. Because the stent material is fluent at this point, adjuvants for promoting healing can be introduced directly into minute fissures and can interpenetrate injured tissue as previously explained.

In a second stage, the stent is solidified in place, after the flowable and bioresorbable stent material has interpenetrated the surrounding endovascular tissue where the stent is to be located. The formation of the stent in place is achieved by the application of a source of activation energy to bring the stent material to a phase activation threshold as previously described. When the stent material is raised to its activation threshold, the flowable stent material changes to a solid state. At this point, all of the stent material, including the portion of the flowable stent material that has interpenetrated fissures in the endovascular wall, becomes solidified and interlocks the stent firmly in place in the blood vessel.

As shown in Figure 3B, the application of pressure pushes the fluent stent material out of the pores of the microporous membrane 110 into an annular recess or space that exists between the surface of the microporous membrane 110 and the surrounding endovascular wall 106 of the blood vessel. This annular recess or space is used as a mold to form the stent. As indicated by the arrows in Figure 3B, the application of fluid or pneumatic pressure forces the fluent

stent material out of the angioplasty balloon and against the surrounding endovascular tissue 106. Some of the fluent stent material permeates the fissures and injured portions of the endovascular wall 106 as shown in Figures 3C and 3D. Upon the application of energy to the fluent stent material, the fluid effects a change of state and becomes substantially solid. It will be appreciated that the fluent material has inter-penetrated narrow fissures and openings in the endovascular wall 106 and thereby forms an inter-linked, anchoring structure which holds the stent firmly in place once it is solidified and the angioplasty balloon is removed as shown in Figure 3D. The bioresorbable material ultimately is absorbed into the tissue and thus enables the tissue to essentially repair itself over time. The stent can include a radiopaque material which facilitates direct fluoroscopic visualization and monitoring of the stent's position and reabsorption.

Referring to Figures 2A-2D and Figures 3A-3D, in another aspect of the invention, the annular space which is created between the surface of the microporous membrane 110 and the surrounding endovascular wall 106 forms a mold cavity 120. A stent is formed in the mold cavity 120 by reaction injection molding, that is by a pressure induced impingement mixing and polymerization or solidification of at least two simultaneously or sequentially introduced reactive fluent components. One or both of the fluent components can include radiopaque markers such as MD-60, organically bound iodine, suspended radiopaque metals such as gold, or a radiopaque material such as barium sulfate or an equivalent radiopaque material capable of being suspended in the fluent composition.

A first reactive fluent component is expelled radially out of the balloon 100, through the microporous surface 110 and into the annular mold cavity as shown in Figures 3B and 4B. The first reactive fluent component is pushed out of the balloon by the application of pneumatic or fluid pressure. A displacement rod having a piston and disposed in the balloon 100 also may be actuated, in accordance with techniques which are well known, to push substantially all of the first reactive component out of the balloon 100 and into the mold cavity 120.

The first reactive fluent component then fills the mold 120, which in effect comprises an annular or cylindrical cavity around the balloon. The outer surface of the mold is defined by the surface of the endovascular wall 106. The inner surface of the mold, which forms the central passageway for the stent, is defined by the microporous membrane surface 110. When the first reactive fluent component is expelled into the mold 120 it also fills and interpenetrates fissures and cracks in the endovascular wall as shown in Figure 3B.

A second reactive fluent component is then introduced into the balloon 100 through a standard catheter tube or hollow tube 108. The second reactive fluent component is likewise pushed radially outward from the porous surface of the balloon 100 into the adjacent mold cavity 120 by pneumatic or fluid pressure or by mechanical means as previously explained.

The injection of the second reactive fluid into the mold cavity 120 can be used as a catalyst to effect a chemically induced polymerization and solidification of both components into a substantially solid stent by compression or impingement mixing of the first and second reactive components. This aspect of the invention is analogous to reaction injection molding. Materials which are capable of polymerization or solidification in the mold are well known. Such materials may be combined with the basic matrix material and adjuvants for forming the stent *in situ* in a stenosed artery, as previously explained.

Alternatively, a single reactive component may be cured or solidified by exposure to optical energy such as UV light having a predetermined intensity sufficient to induce photopolymerization or photo curing. In this case, the balloon surface must be transmissive with respect to the source of optical energy.

In an aspect of the invention, the polymerization or solidification of the reactive fluent stent material in the mold cavity can be used to govern the final morphology, modulus and other mechanical or physical properties of the stent. Thus, the mold cavity formed by the balloon surface and surrounding endovascular wall can function much as a batch reactor for conducting a chemical or photochemical reaction. Reaction parameters such as the pressure, temperature and times for injecting reactor fluids into the mold are controlled in

accordance with techniques which are well known to ensure that a desired modulus, homogeneity, or physical property is imparted to the stent being formed in the mold.

Another aspect of the invention is shown with reference to Figures 4A-4D. In a preferred embodiment, a bioresorbable stent material 200 is provided in a particulate filament, fiber or woven form as shown in Figure 4A. The woven or fibrous bioresorbable filament 200 is woven about the cylindrical surface of a flexible, expandable balloon or hollow catheter tube 202. The hollow catheter tube 202 comprises a microporous membrane surface 204. Referring to Figure 4A, the fibrous, bioresorbable filament material 200 may also take the form of a suture-like thread woven into a loose network structure with a cylindrical shape about the surface of the microporous membrane 204.

The provided filament material can include a radiopaque marker such as a radiopaque dye or coating of a radiopaque material which does not affect the flexibility of the fiber. Alternatively, the composition of the fiber may include a radiopaque marker in accordance with techniques which are well known.

The hollow catheter tube 202 is shown for simplicity and by way of example. Equivalent structures may substituted for hollow catheter tube 202 such as an angioplasty balloon, or equivalent flexible cylindrical container comprising a microporous membrane capable of expansion upon the application of an internal pressure. The purpose of the flexible microporous membrane surface is to enable a quantity fluent matrix material for the stent to be advanced along a path of travel in a blood vessel 205 as shown in Figure 4A.

The hollow catheter tube 202 is advanced along a path of travel to an injured section of the blood vessel wall or to an aneurysm as shown in Figure 4A. The catheter 202 may be advanced along the path of travel by a guidewire 102 or simply by pushing on a portion of nonporous catheter tube 108 as explained previously with respect to Figures 1A and 1B. The aspect of the invention shown Figures 4A-4D has a further advantage. In its collapsed form, the pliant net of bioresorbable filament material 200 surrounding the catheter

tube 202 results in minimal trauma to the blood vessel intima surface or endothelial lining during insertion and transport to the aneurysm site.

The hollow catheter tube 202 holds a quantity of reactive bioresorbable matrix material in fluent form as explained previously with reference to the reaction injection molding embodiment. The fluent bioresorbable matrix material is contained by the microporous membrane surface 204 of the hollow catheter tube 202. This enables the fluent bioresorbable matrix material to be transported to the aneurysm site in the blood vessel 205 along with the expanded reenforcing mesh of filament material 200 which is woven around the outside surface of the cylindrical microporous membrane 204. It will be appreciated that an annular recess 220 is formed between the microporous membrane surface 204 and the surrounding blood vessel wall 205. The annular recess 220 provides a mold for casting a stent in place as shown in Figures 4B-4D.

The fluent matrix material contained by the microporous membrane surface 204 is chosen to be reactive with the woven reenforcing mesh of bioresorbable filament material 200. When the hollow catheter tube 202 is advanced to the target site, fluid or pneumatic pressure is applied through nonporous catheter tube 108 and expands the flexible microporous membrane surface 204 and the surrounding expandable reenforcing mesh of stent filament material 200. As shown in Figure 4B, the fluent matrix material is then deposited throughout the surrounding mesh of stent filament material 200. The surrounding mesh of filament material and the fluent matrix material then expand into and enter the annular space 220 which forms the mold cavity. The expandable reenforcing mesh of bioresorbable filament material 200 is then conformably pressed against the blood vessel wall 205 by the radial pressure of the fluent matrix material and the expanded catheter tube 202 as shown in Figures 4B and 4C. As the fluent matrix material is extruded through the microporous membrane 204 it engulfs the expanded net of reenforcing mesh or filament material 200. At this point, some of the fluent matrix material also interpenetrates fissures in the surrounding blood vessel wall 205.

Referring to Figures 4B and 4C, the application of energy to the engulfed mesh material 200 sets the material and begins the process of solidifying the stent. Depending upon the nature of the reaction between the filamentous woven bioresorbable filler material and the fluent stent material extruded from the microporous membrane, the amount of energy necessary to set or to coalesce the stent can be minimized. For example, a reactive fluent matrix material can be extruded from the microporous membrane 204 in a heated form to substantially react with the fibrous or filamentous woven stent material and thereby substantially solidify a stent without the application of additional amounts of energy.

Alternatively, the fluent matrix material can be chosen to react with a bioresorbable, woven filament material upon the application of electrical, optical, ultrasound or heat energy provided from within the hollow catheter as shown in Figure 4C. This would have the advantage that additional amounts of fluent stent material could be extruded through the microporous membrane, through the loosely woven bioresorbable filler and could then interpenetrate fissures and breaks in the surrounding endovascular wall of the blood vessel 205. This would have the advantage that additional amounts of fluent stent material could interpenetrate fissures and breaks in the endovascular wall. The use of a reactive fluent material which is forced out of microporous membrane 204 to react with the woven mesh of bioresorbable filler material can provide a stent whose morphology, stiffness, characteristics and configuration can be closely controlled in accordance with techniques which are well known.

In Figure 4D, a stent 230 has been molded in place to form a substantially cylindrical shell that interpenetrates surrounding endovascular tissue of blood vessel 205. The microporous membrane 204 is then withdrawn as shown leaving a central lumen or passageway through the stent 230 for the free movement of blood.

It will be appreciated that the microporous membrane 204 can be textured to provide a smooth central lumen upon withdrawal of the catheter 202. This provides the advantage of an extremely smooth surface through the center

of the stent 230 for enhanced blood flow. This aspect of the invention also provides the advantage of obviating the problems often encountered from the contact of sutures with flowing blood, such as thrombosis and cell deposition, because the fibers are safely sealed into the bulk of the stent matrix material upon its solidification. Figure 4D shows a finalized molded stent 230 with embedded reenforcing mesh or filament material 200. Note that the fibers comprising the expandable reenforcing mesh or filament material 200 are now safely sealed into the bulk of the stent matrix material which was extruded in fluent form through microporous membrane 204 and then solidified. The preferred embodiment shown in Figures 4A-4D thus provides a bioresorbable, fiber net reenforced stent which has the advantage of being much more resistant to radial expansion than a conventional stent.

A preferred bioresorbable stent material that is activated by the application of energy to effect a change of state and interlink with fissures in the endovascular wall comprises the following:

A protein, glycoprotein and/or polysaccharide and a liquid vehicle electrolyte capable of dissolving or suspending the protein, glycoprotein or polysaccharide.

The liquid vehicle electrolyte comprises an aqueous solution with sufficient ionic strength to conduct electric current or RF energy. Preferably the liquid vehicle electrolyte comprises water and ionized inorganic or organic based salts or poly-salts.

A radiopaque or Ro-contrast sterile IV solution can be added to the foregoing fluent material to provide direct, real time fluoro-visualization. The radiopaque material may comprise barium sulfate, a suspension of radiopaque metal such as gold particles which are small enough to remain in suspension, or a material such as MD-60 organically bound iodine such as is manufactured MALLINCKRODT.

Optionally, the flowable stent material also includes an insoluble network reinforcement agent and adjuvants to promote wound healing.

Examples of compositions which can be used for the stent material will include:

1. A matrix material comprising a protein, glyco-protein or polysaccharide: Collagen, fibrin, elastin, fibronectin, vironectin, aglin, albumin, laminin, gelatin, cellulose, modified cellulose, starch, modified starch, synthetic polypeptide; acetylated, sulfonated or phosphorylated collagen, glycosaminoglycans (heparin, heparan, dermatan, chrondoin sulfate);

2. Optionally, a liquid vehicle electrolyte comprising aqueous saline, calcium chloride;

3. Optionally, a reinforcing material comprising poly(lactide), poly (glycolide), poly (lactide)-co-glycolide, poly (caprolactone), poly (betahydroxtbutylate), poly (anhydride), or a poly (orthoester).

The liquid vehicle electrolyte should be used if RF energy is the source of activation energy applied to effect the change of phase of the stent material. All of the reinforcing agents in paragraph 3 above are bioresorbable polymers. They may aid the ionic strength of the liquid vehicle compositions in paragraph 2. If the ionic strength of aqueous saline or calcium chloride is high enough, it also can assist in lysing some of the cells. This advantageously may provide a tissue surface that is more readily interpenetrated and bondable by the stent material as it assumes solid state. The compositions in paragraph (1) (matrix material) and (2) (liquid vehicle electrolyte) are the compositions which most often can be used for the stent material. The molecules of the foregoing compositions are of a size that can pass through the pores of the balloon.

Preferred sealer compositions are well known and can be duplicated by those skilled in the art without undue experimentation. Such sealer compositions should first bond well to tissue surfaces, undergo a volume contraction during the radio frequency (RF) treatment and become "leathery" with a continuous unbroken surface. Below the surface, the sealant material should exhibit a general "network" structure at the molecular level to provide both mechanical integrity between the bonded tissue surfaces and to provide

pathways for cell growth during epithelialization and tissue regeneration. To this end, the RF treated sealer composition is bioresorbable. The cross-links in the network structure are provided by a combination of physical properties (crystalline-oriented regions, entanglements) and chemical properties (hydrogen bonding, ionic bonding and covalent bonding).

A flowable stent material that would be expected to respond to RF energy and effect a change of state from a fluent to a solid material should have the following properties:

contain ample hydrogen bonding sites;

preferably contain ionized groups;

be able to interpenetrate with and form good interactions with tissue structures and tissue components such as proteins, etc.;

exhibit structural regularity (for example, helix forms) for inducing fibril formation and interfibril association;

provide reactive sites for covalent bonding of the stent material to surrounding tissue and of the stent material to itself to form an internal network. Examples are the epsilon amino group on lysine, the hydroxy group on hydroxy proline and other equivalent compositions.

Physically, the preferred stent material undergoes a change of state from a fluent material to a non-flowable, substantially solid material upon the application of activation energy of a predetermined threshold for initiating the change of state. The change of state is effected by a microstructural transformation such as the changing of a lattice network in response to a temperature above the activation threshold as is well known. In the case of a photo polymer or photoforming agent, the activation energy comprises optical energy having a sufficient intensity to effect photo initiation and/or photo polymerization in accordance with techniques which are well known.

If the material is soluble, it should become insoluble or merely swellable in the vehicle electrolyte. If the fluent material is insoluble, but a suspension or emulsion, it should become coagulated and not be resuspendable when in solid

form. Rheologically, the preferred material should become more elastic with greater out of phase shear stress response. A net volume contraction should be observable due to loss of the aqueous vehicle to tissue and air as well as conformational changes and chemical shrinkage from cross-linking.

In a preferred embodiment, the material that comprises the body of the stent consists of four (4) components; a protein; a glycoprotein or polysaccharide, a liquid vehicle electrolyte added for conducting RF energy to effect the change of state from a flowable material to a solid, an insoluble yet bioresorbable network reinforcement agent and an adjuvant to promote wound healing such as heparin or its derivatives.

As set forth previously, a radiopaque component is also provided in the stent material to render the stent amenable to direct, real time fluoro-visualization. The marker material may comprise any radiopaque material such as organically bound iodine, particles of radiopaque elements such as gold, or other radiopaque materials capable of remaining in suspension while the stent material is in a fluent state and retaining the property of radiopaqueness when the fluent material is solidified into the stent.

There are several alternate methods for activating the stent material to its phase activation threshold for effecting a change of phase from a fluent state to a solid. The term activation energy as defined herein includes the application of both heat and optical energy at a minimum intensity sufficient to effect a change of phase from a fluent material to a solid state in accordance with methods which are well known.

Referring to Figure 5A, an RF energy source 300 is coupled through a catheter tube 302 to a metallized balloon 304. Preferably, the balloon 304 has a metallized or conductive microporous surface for conducting RF energy (shown by arrows) into the adjacent stent material (not shown). It is understood that the fluent stent material is extruded into an annular mold cavity created between the surface of balloon 304 and a surrounding cylindrical wall of a blood vessel as shown in Figures 4A-4D.

In Figure 5B a primary matrix for the stent material comprises a photo initiator or photo polymer material which is changed from a fluent to solid state upon the application of optical energy of a predetermined intensity such as ultraviolet (UV) light of a predetermined wavelength to effect polymerization for the change of the stent material to a solid state. The fluid stent material can also contain a radiopaque material. Referring to Figure 5B, the balloon 304 comprises a flexible microporous surface material transmissive to ultraviolet light or to another source of optical energy. The source of optical energy 310 is conducted to the hollow catheter 302 through a fiber optic cable 312 in accordance with techniques which are well known. A conventional optical emitter 314 is positioned within the balloon 304 for irradiating the surrounding stent material with a source of optical energy necessary to achieve photo polymerization in accordance with techniques which are well known. The fluent stent material is extruded from the microporous surface of balloon 304. Thus, the fluent stent material is disposed radially about the surface of the balloon 304. The optical energy from the emitter 314 irradiates the surrounding stent material equally and effects a substantially complete polymerization and solidification of the stent material about the microporous surface of balloon 304 which acts as a mold surface.

Alternatively, the optical emitter 314 may comprise any conventional means for emitting optical energy of a predetermined intensity to effect photo polymerization. For example, the emitter 314 could be a microlens integrated onto a surface emitting laser. The microlens, as in the case of a conventional optical emitter, is disposed within the balloon 304 and can be irradiated by a collimated beam from a conventional laser through fiber optic cable 312.

Figure 5C shows an alternate method for applying source of activation energy to a fluent stent material. An expandable, flexible balloon 304 comprises a microporous surface. A quantity of stent material is placed in the hollow catheter tube 302 and extruded through the microporous surface of balloon 304 by the application of pneumatic or fluid pressure as previously explained. An electrical source 316 is coupled through catheter tube 302 to a piezo electric

crystal or ultrasound emitter 318 which is positioned within the expandable balloon 304. The piezo electric crystal or ultrasonic transducer 318 is activated in accordance with techniques which are well known to apply an activation energy shown by the arrows in Figure 5C to the stent material which has been extruded through the microporous surface of balloon 304.

As shown in Figure 6, a means for heating a flowable stent material to effect a change of state to a solid material also may comprise a resistive heating element 400 incorporated within the microporous balloon 402. As previously described, a flowable stent material 404 is extruded through the microporous surface of balloon 402 by the application of pressure. The flowable stent material can include a radiopaque marker to render the flowable stent material 404 radiopaque as previously explained. A mold cavity is created between the surface of balloon 402 and the surrounding wall of a blood vessel 420. Once a sufficient amount of radiopaque flowable stent material 404 has been delivered to an intervention site in the vessel through the porous balloon 402, a source of electrical energy 408 activates the resistive heating element 400 to the phase activation threshold. The heat energy from the resistive heating elements 400 then is conducted radially outward to the radiopaque flowable stent material 404 and effects a change of state to a solid, thus forming a radiopaque stent *in situ* at the site of intervention. According to this aspect of the invention, resistive heating also may be accomplished through a distributed array of flexible, malleable resistive heating elements provided over the surface of the porous balloon 402 in accordance with techniques which are well known. An array of resistive heating elements may be deposited, laser welded or otherwise provided over the outer surface of the balloon 402. This would have the advantage that the heating elements would be disposed in direct contact with the mold surface formed by the balloon 402 and thus could provide direct and immediate conduction of heat energy to the flowable stent material 404.

Referring to Figure 6, in accordance with another aspect of the invention, adaptive feedback is used to closely control the delivery of stent material through the porous angioplasty balloon 402. A source of fluent material 404 is capable

of effecting a change of state upon the application of energy to a predetermined threshold. This source of stent material can be completely contained within the balloon 402. Alternatively, the source of the stent material can be provided in a chamber or reservoir 410 which is located external to the porous balloon 402 and is in fluid communication with the balloon 402 through a line 412 connected to the central lumen of catheter tube 302 as in the example shown in Figure 6. The fluent material is expelled through pores in the balloon 402 by any convenient method. This could be done by an increase in pressure, or by the addition of air, or merely heating the stent fluid to a point such that it expands and is expelled through the pores of the balloon, but does not reach the activation threshold.

A pressure sensor 416 can be any convenient microelectronic pressure sensor for sensing either a pressure drop within the balloon 402 or pressure on the surface of the balloon 402. The object is to equalize pressure over the surface of the balloon 402 to a predetermined threshold which would be compatible with expanding the stent material into fissures of the surrounding blood vessel 420, without damaging endovascular tissue. Once the predetermined pressure is reached, signals from the pressure sensor are provided to a signal processor 418 for amplification in accordance with techniques which are well known. An amplified control signal from the signal processor 418, indicative that a predetermined pressure has been reached, is then applied in a well known manner to block further introduction of stent material into the balloon through line 412. Also, signals from the signal processor 418 are applied to the electrical energy source to activate the resistive heating element 400 and to initiate the heat activation to solidify the stent. This has the effect of preventing further stent material from being expanded through the pores of the balloon 402. The adaptive control system prevents overexpansion of the balloon and prevents excess bioresorbable material from entering the artery or blood vessel.

A radiopaque component can be added to the stent material to render both the fluent form and the subsequent cured, non-fluent form of the stent

radiopaque. The radiopaque component can advantageously obviate the need for the foregoing adaptive feedback control. In an alternate embodiment, the radiopaque fluent stent material is introduced to the stenosed region under direct fluoro-visualization in real time. This enables direct observation of the precise manner in which the fluent stent material is distributed against the end of vascular wall through the microporous membrane. The use of the radiopaque marker thereby enables the physician to carefully control the extrusion of flowable stent material into the blood vessel and advantageously avoids fluent stent material overflow and vessel damage. Since the extrusion of the radiopaque stent material can be directly observed in real time, the positioning of the stent and the precise amount of fluent stent material extruded from the microporous membrane can be closely controlled. This advantageously can obviate the need for adaptive feedback control and can advantageously decrease manufacturing cost complexity and the overall cost of a device constructed in accordance with this aspect of the present invention.

It will be appreciated that the ability to create a stent *in situ* and in living tissue provides significant advantages which are not achievable by a conventional endovascular stent and delivery system. Referring to Figures 7A and 7B, a further aspect of the present invention provides a custom shaped balloon 500 which enables a stent to be created *in situ* with a predetermined geometry by a process of casting in place against a uniquely configured mold surface.

The surface of balloon 500 is configurable to form a mold surface which is capable of inducing a desired geometry in the finalized stent 510. The surface of balloon 500 can be uniquely designed to create a primary mold surface against which the extruded stent material is cast. The shape of the mold cavity is defined by both the surface of the custom shaped balloon 500 and the surrounding endovascular wall 502 of the blood vessel in which the balloon is positioned. As the balloon 500 expands, its surface pushes the extruded stent material conformably against the endovascular wall 502 and into fissures and breaks in the endovascular wall 502 as shown in Figure 7A.

As shown in Figure 7A, an angioplasty balloon 500 may be custom shaped or preformed in a desired configuration to influence the flow of blood through a stenosed artery. The surface of the balloon 500 may be uniquely configured such that it forms a mold which imparts a desired shape to the stent. For example, the mold may be configured with a series of ridges or other geometry to maximize blood flow or to induce turbulent flow and reduce thrombogenic sites.

As shown in Figures 7A-7B, a microporous surface of a balloon 500 comprises a series of ridges for creating a predetermined geometric shape for the annular mold cavity 504 into which the fluent stent material (indicated by dots in Figure 7A) is cast, as previously explained. The addition of an irregular shaped surface such as ridges on balloon 500 also can have the effect of maximizing the surface area of the stent 510 in contact with the endovascular wall and thereby increases the potential for interlinking the stent material with endovascular tissue. It will be appreciated that an aspect of the present invention provides a mold cavity 504 which can have a specific surface configuration which may be optimized for each patient's particular physical characteristics or conditions which are present at a stenosed artery or blood vessel. The form of mold cavity 504 could be changed for each intervention site in order to optimize the therapeutic effect. Such flexibility is made possible by the fact that the stent 510 is created *in situ*. That is, a stent according to an aspect of the invention is cast in a mold 504 defined by the surface of the endovascular wall 508 and the porous surface of the angioplasty balloon or catheter tube 500 or either flexible containment vessel. Thus, the stent is created anew *in situ* at the site of each intervention.

The foregoing aspects of the invention provide advantages in an enhanced therapeutic effect for treating stenosed arteries, which has not been possible up to now. Because an aspect of the invention casts a stent in a mold from a fluent to a non-fluent state, this would enable a physician to repair precisely the unique surface configuration of the injured arterial in question. For example, because the stent is cast from a mold defined by the endovascular wall

and the surface of the microporous balloon, a maximum amount of fluent stent material can be provided in the mold to interpenetrate and substantially fill fissures in the endovascular wall.

The mold can be preconfigured to determine exactly the degree of roughness or smoothness to be imparted to the endovascular wall. Each mold surface could be individually provided with an optimized configuration to impart desired geometrical features onto the interior surface of the artery or blood vessel for enhancing blood flow and preventing the recurrence of thrombogenic conditions.

While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments, but on the contrary is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims.

CLAIMS

What is claimed is:

1. A stent comprising:

a bioresorbable material molded *in situ* in a blood vessel from a fluent material capable of assuming a solid state upon the application of energy above an activation threshold, said bioresorbable material chosen from the group consisting of:

a protein, glycoprotein, polysaccharide, mucosaccharide and;

a liquid vehicle electrolyte capable of dissolving or suspending said protein, glycoprotein, mucosaccharide and polysaccharide and;

2. A stent according to claim 1 further comprising a substantially insoluble network reinforcement agent;

3. A stent according to claim 2 further comprising an adjuvant to promote wound healing;

4. A stent according to claim 1 wherein said protein is selected from the group consisting of:

collagen, fibrin, elastin, fibronectin, vironectin, algin, albumin, laminin, gelatin, synthetic poly(peptide).

5. A stent according to claim 1 wherein said liquid vehicle electrolyte is selected from the group consisting of:

aqueous saline, aqueous calcium chloride.

6. A stent according to claim 2 wherein said network reinforcement agent is selected from the group consisting of:

poly(lactide), poly(glycolide), poly(lactide-co-glycolide), poly(caprolactone), poly(beta hydroxtbutylate), poly(anhydride), poly(orthoester).

7. A stent according to claim 3 wherein said adjuvant to promote wound healing is selected from the group consisting of:

herparan; heparin; a glycosaminoglycan.

8. A stent formed *in situ* in a blood vessel, artery, or the like characterized by a substantially cylindrical vascular wall, the stent formed by reactive injection molding comprising the steps of:

providing first and second reactive fluid components which react with each other to form a solid when mixed by impingement;

advancing a balloon having a porous surface including a supply means for sequentially providing a quantity of said first and second reactive fluid components to said balloon;

advancing the balloon along the blood vessel to a stenosed region such that the balloon is encompassed by an annular recess defined by the surface of the vascular wall of the blood vessel and the surface of the balloon;

injecting a quantity of the first reactive fluid into the annular recess;

injecting a quantity of the second reactive fluid into the annular recess such that it mixes by impingement with said first reactive fluid and solidifies in the annular recess;

removing the balloon to form a stent having a central passageway for enhanced blood flow.

9. A stent created in situ in a blood vessel characterized by a substantially cylindrical wall by the process of:

providing a bioresorbable thread-like filler material woven loosely about a substantially cylindrical microporous membrane;

providing a quantity of fluent matrix material within the microporous membrane, said fluent matrix material capable of undergoing a change of state to a solid upon the application of energy at a threshold activation level;

advancing the microporous membrane and thread-like material to a target site in the blood vessel;

expanding the microporous membrane to push the thread-like filler material against the blood vessel wall;

extruding the fluent matrix material to engulf said thread-like filler material;

applying a source of energy to said engulfed thread-like material to solidify the matrix material such that the filler material provides a fiber reinforced network sealed within the solidified matrix material;

removing the microporous membrane from the blood vessel.

10. A bioresorbable, radiopaque stent formed in a blood vessel, or the like comprising:

a radiopaque, bioresorbable body formed *in situ* in the blood vessel by the process of extruding a fluent, radiopaque bioresorbable stent material from a microporous angioplasty balloon inserted in said blood vessel; and

apply energy at an activation threshold sufficient to solidify said extruded fluent stent material;

withdrawing the angioplasty balloon from the blood vessel to provide a central lumen for the stent.

11. A stent comprising:

a bioresorbable material molded *in situ* in a blood vessel from a fluent material capable of assuming a solid state upon the application of energy above an activation threshold, said bioresorbable material chosen from the group consisting of:

a protein, glycoprotein, polysaccharide, mucosaccharide and;

a liquid vehicle electrolyte capable of dissolving or suspending said protein, glycoprotein, mucosaccharide and polysaccharide and;

a radiopaque IV solution capable of retaining its radiopaqueness in said solid state.

12. A stent according to claim 11 further comprising a substantially insoluble network reinforcement agent;

13. A stent according to claim 12 further comprising an adjuvant to promote wound healing;

14. A stent according to claim 11 wherein said protein is selected from the group consisting of:

collagen, fibrin, elastin, fibronectin, vironectin, algin, albumin, laminin, gelatin, synthetic poly(peptide).

15. A stent according to claim 11 wherein said liquid vehicle electrolyte is selected from the group consisting of:

aqueous saline, aqueous calcium chloride.

16. A stent according to claim 12 wherein said network reinforcement agent is selected from the group consisting of:

poly(lactide), poly(glycolide), poly(lactide-co-glycolide), poly(caprolactone), poly(beta hydroxtbutylate), poly(anhydride), poly(orthoester).

17. A stent according to claim 13 wherein said adjuvant to promote wound healing is selected from the group consisting of:

herparan; heparin; a glycosaminoglycan

18. A radiopaque stent formed *in situ* in a blood vessel, artery, or the like characterized by a substantially cylindrical vascular wall, the stent formed by reactive injection molding comprising the steps of:

providing first and second radiopaque reactive fluid components which react with each other when mixed by impingement to form a solid;

advancing a balloon having a porous surface including a supply means for sequentially providing a quantity of said first and second radiopaque reactive fluid components to said balloon;

advancing the balloon along the blood vessel to a stenosed region such that the balloon is encompassed by an annular recess defined by the surface of the vascular wall of the blood vessel and the surface of the balloon;

injecting a quantity of the first radiopaque reactive fluid into the annular recess;

injecting a quantity of the second radiopaque reactive fluid into the annular recess such that it mixes by impingement with said first radiopaque reactive fluid and solidifies in the annular recess;

removing the balloon to form a radiopaque stent having a central passageway for enhanced blood flow.

19. A stent created in situ in a blood vessel characterized by a substantially cylindrical wall by the process of:

providing a bioresorbable thread-like filler material woven loosely about a substantially cylindrical microporous membrane;

providing a quantity of radiopaque fluent matrix material within the microporous membrane, said fluent matrix material capable of undergoing a change of state to a solid upon the application of energy at a threshold activation level;

advancing the microporous membrane and thread-like material to a target site in the blood vessel;

expanding the microporous membrane to push the thread-like filler material against the blood vessel wall;

extruding the radiopaque fluent matrix material to engulf said thread-like filler material;

applying a source of energy to said engulfed thread-like material to solidify the matrix material such that the filler material provides a fiber reinforced network sealed within the solidified radiopaque matrix material;

removing the microporous membrane from the blood vessel.

20. A method for treating a stenosed or otherwise injured region of an endovascular wall of a blood vessel comprising:

providing a bioresorbable material capable of undergoing a change in phase from a fluent state to a solid state upon the application of energy above a phase activation threshold;

introducing through said blood vessel to said stenosed or injured region of the endovascular wall an angioplasty balloon having a porous surface, said balloon containing a quantity of said bioresorbable material in a fluent state;

expelling said fluent bioresorbable material through the porous surface of the containment vessel into a mold having a first surface defined by the endovascular wall and a second surface defined by said balloon;

applying a source of energy above the phase activation threshold to said bioresorbable material to effect said change of phase to a solid state;

removing said balloon to provide a smooth channel for enhanced blood flow.

21. A method for treating a stenosed region of a blood vessel according to claim 1 wherein the step of expelling said fluent bioresorbable material further includes the step of inter-penetrating fissures and breaks in said stenosed region of said blood vessel with the fluent bioresorbable material.

22. An improved method for balloon angioplasty comprising:

providing a bioresorbable stent material capable of effecting a phase transition from a fluent state to a solid state upon the application of a source of energy above an activation threshold;

providing a container having a porous surface for holding a quantity of said stent material in a fluent state;

advancing said container through a blood vessel comprising a substantially cylindrical endovascular wall to a target site therein;

extruding the fluent stent material through the porous surface of the container such that the fluent stent material fills a space between the surface of the container and the surrounding endovascular wall;

applying a source of activation energy to effect said phase transition to a solid state to form a stent;

removing the container to form a passageway for enhanced flow of blood through the stent.

23. A method for treating a stenosed or otherwise injured region of an endovascular wall of a blood vessel, artery or the like;

providing a quantity of bioresorbable material capable of effecting a change of state from a fluent material to a solid upon heating said material to an activation threshold temperature;

providing a catheter balloon comprising a porous membrane for holding a quantity of said bioresorbable material in a fluent state;

introducing said catheter balloon at the stenosed region;

extruding said quantity of fluent bioresorbable material into a mold cavity defined by the endovascular surface of said blood vessel and the porous membrane of said catheter balloon;

heating the catheter balloon to the activation threshold to solidify said bioresorbable material to form a stent;

removing said catheter balloon to provide a central passageway through said stent for the free passage of blood.

24. A method for treating a stenosed or otherwise injured region of a blood vessel according to claim 23 including the step of preconfiguring the porous membrane of the catheter balloon to form desired geometric features in the surface of the finished stent.

25. A method for treating a stenosed or otherwise injured region of a blood vessel according to claim 24 wherein the porous membrane of said catheter balloon is configured with a series of ridges to provide a maximized surface area for interlinking the extruded stent material with the adjacent endovascular wall.

26. A method for treating a stenosed or otherwise injured region of a blood vessel according to claim 24 wherein said catheter balloon is configured to have a smooth surface for forming a smooth central passageway through the stent for enhancing blood flow and substantially eliminating thrombogenic sites.

27. A method for forming a stent *in situ* for repairing the wall of a tubular, vascular structure, such as a blood vessel or like comprising the steps of:

providing a quantity of fluent stent material in a catheter balloon having a porous surface;

positioning the balloon within the blood vessel such that the porous surface of the balloon is surrounded by the wall to be repaired;

forming a mold defined by an annular space between said porous balloon surface and said surrounding wall;

forcing a quantity of said fluent stent material through said porous balloon surface into said mold;

applying a source of energy to said fluent stent material at an activation threshold to effect the phase transition of said fluent material to a solid state and form a stent in said mold;

removing said balloon from said blood vessel.

28. A method according to claim 27 wherein the step of effecting a change of state from a fluent material to a solid comprises the steps of:

providing a plurality of resistive heating elements on said balloon surface;

applying an electric current to said resistive heating elements such that the elements heat the extruded stent material to an activation threshold sufficient to effect the phase transition to a solid.

29. A method according to claim 27 wherein the step of effecting a change of state to a solid comprises the steps of:

providing a balloon having a metallized porous surface;

applying radio frequency energy to said metallized surface to heat the extruded stent material to the activation threshold sufficient to effect the phase transition to a solid.

30. A method according to claim 27 wherein said step of effecting a change of state from a fluent material to a solid comprises the steps of:

providing an optical emitter in the balloon;

providing a fiber optic coupling to said optical emitter;

supplying through said fiberoptic coupling a source of optical energy of sufficient intensity to effect photopolymerization of the fluent stent material.

31. A method according to claim 27 wherein said step of effecting a change of state to a solid comprises the steps of:

providing a balloon surface receptive to heating by the application of ultrasound energy;

applying a source of ultrasound energy to heat said balloon surface such that adjacent stent material is raised to its phase activation temperature and transitions to a solid state.

32. A method for forming a bioresorbable stent in place in a blood vessel for repairing a stenosed or injured wall of the blood vessel comprising the steps of:

providing a porous balloon containing a quantity of fluent, bioresorbable stent material capable of undergoing a phase transition from a fluent state to a solid state when a source of energy at a phase activation threshold is applied to the stent material;

introducing said porous balloon to a stenosed site within said blood vessel such that an annular space is formed between the wall of the blood vessel and the balloon surface;

increasing the pressure within said balloon such that the fluent stent material is injected into said annular space;

applying a source of activation energy to said fluent material to effect said change of phase to a solid state;

removing the balloon from said blood vessel.

33. A method for creating a bioresorbable stent in place in a blood vessel comprising:

providing a balloon having a porous surface, said balloon containing a quantity of fluent bioresorbable material capable of undergoing a change of phase to a solid state when subjected to a source of energy sufficient to effect to a phase activation;

introducing said balloon to a stenosed region of a blood vessel, said blood vessel comprising a substantially cylindrical wall including fissures in said wall;

expelling the fluent stent material from said balloon through said porous surface such that the fluent stent material interpenetrates said fissures in said wall and fills a space between said balloon surface and said wall;

applying a source of energy to said fluent material to effect said change of phase to a solid state thereby providing a stent having an outer surface

interlinked with said vascular wall and an inner surface smoothed by said balloon surface;

removing said balloon to provide an enhanced passage for blood flow.

34. A method for forming a bioresorbable stent *in situ* for repairing the wall of a blood vessel or the like comprising:

providing a quantity of bioresorbable material capable of undergoing a change of phase from a flowable form to a solid upon the application of optical energy of sufficient intensity to effect the phase activation;

introducing a balloon filled with said quantity of bioresorbable fluent material to a stenosed region of the blood vessel, said balloon comprising a porous surface transparent to said optical energy;

forming a mold defined by an annular space between the endovascular wall and surface of the porous balloon;

injecting the fluent material into said mold;

irradiating the fluent material with optical energy of sufficient intensity to photoform the fluent material into a solid;

removing the balloon to provide a smooth central lumen through said solid material for enhancing blood flow.

35. A method for forming a bioresorbable stent according to claim 34 further comprising the steps of:

providing an optical emitter in said balloon for irradiating the injected stent material;

coupling said optical emitter to a source of optical energy of sufficient intensity to solidify the injected stent material.

36. A method for creating a stent in situ in a blood vessel, or the like having a substantially cylindrical vessel wall comprising:

providing a quantity of a stent matrix material in a flowable form contained in a catheter balloon comprising a substantially cylindrical microporous membrane;

providing a fibrous bioresorbable filler material woven in a net-like structure about said microporous membrane;

advancing the catheter balloon along a path of travel within said blood vessel to a target site for medical intervention;

expanding the catheter balloon such that the bioresorbable filler material is advanced to the vessel wall;

extruding the flowable stent matrix material through the microporous membrane to engulf the bioresorbable material;

applying a source of energy to solidify the flowable matrix material such that the fibrous bioresorbable material is sealed in the solidified matrix material;

removing the catheter balloon from said vessel.

37. A method according to claim 36 wherein said bioresorbable material comprises a suture-like thread woven in a network structure and loosely adhered around said catheter balloon.

38. A method for treating an aneurysm or dissected site in a blood vessel characterized by a substantially cylindrical wall comprising:

providing a catheter balloon having a microporous membrane for containing a quantity of stent matrix material in a fluent form;

providing a suture-like bioresorbable filler material woven in a loose net about said microporous membrane;

advancing said catheter balloon to a target site in said blood vessel;

expanding the catheter balloon to push the net of suture-like filler material against the cylindrical wall of said blood vessel;

extruding the fluent stent material through the microporous membrane to engulf said net of suture-like material;

applying a source of energy to solidify said fluent matrix material such that the thread-like suture material is sealed therein;

removing the microporous membrane from said blood vessels to provide a free passage for blood flow.

39. A method for treating a stenosed or injured region of a blood vessel comprising:

providing a bioresorbable fluent material capable of undergoing a change of state to a substantially solid material upon the application of energy above a phase activation threshold;

adding a radiopaque IV solution to the fluent bioresorbable material;

providing an angioplasty balloon comprising a microporous membrane surface;

filling the angioplasty balloon with a quantity of the fluent bioresorbable, radiopaque material;

advancing the angioplasty balloon to said stenosed region;

extruding the bioresorbable radiopaque material through the microporous membrane into a cavity formed between the microporous membrane surface and the blood vessel wall;

observing through direct fluoro-visualization the distribution of the radiopaque, bioresorbable fluent stent material as it is extruded through said microporous membrane surface;

applying energy above said phase activation threshold to solidify said radiopaque bioresorbable material;

withdrawing said angioplasty balloon to thereby form a solidified, radiopaque and bioresorbable stent.

40. A method according to claim 39 wherein said radiopaque bioresorbable stent is observable under direct fluoro-visualization over the long term to ensure proper positioning and reabsorption into the blood vessel.

41. A method for treating a stenosed or otherwise injured region of an endovascular wall of a blood vessel, artery or the like;

providing a quantity of radiopaque, bioresorbable material capable of effecting a change of state from a fluent material to a solid upon heating said material to an activation threshold temperature;

providing a catheter balloon comprising a porous membrane for holding a quantity of said radiopaque bioresorbable material in a fluent state;

introducing said catheter balloon at the stenosed region;

extruding said quantity of fluent, radiopaque, bioresorbable material into a mold cavity defined by the endovascular surface of said blood vessel and the porous membrane of said catheter balloon;

heating the catheter balloon to the activation threshold to solidify said bioresorbable material to form a stent;

removing said catheter balloon to provide a central passageway through said stent.

42. A method for treating a stenosed or otherwise injured region of a blood vessel according to claim 41 including the step of preconfiguring the porous membrane of the catheter balloon to form desired geometric features in the surface of the finished stent.

43. A method for treating a stenosed or otherwise injured region of a blood vessel according to claim 42 wherein the porous membrane of said catheter balloon is configured with a series of ridges to provide a maximized surface area for interlinking the extruded stent material with the adjacent endovascular wall.

44. A method for treating a stenosed or otherwise injured region of a blood vessel according to claim 42 wherein said catheter balloon is configured to have a smooth surface for forming a smooth central passageway through the stent for enhancing blood flow and substantially eliminating thrombogenic sites.

45. A method for forming a radiopaque stent *in situ* for repairing the wall of a tubular, vascular structure, such as a blood vessel, or like comprising the steps of:

providing a quantity of radiopaque fluent stent material in a catheter balloon having a porous surface;

positioning the balloon within the blood vessel such that the porous surface of the balloon is surrounded by the wall to be repaired;

forming a mold defined by an annular space between said porous balloon surface and said surrounding wall;

forcing a quantity of said radiopaque fluent stent material through said porous balloon surface into said mold;

applying a source of energy to said fluent stent material at an activation threshold to effect the phase transition of said fluent material to a solid state and form a stent in said mold;

removing said balloon from said blood vessel.

46. A method according to claim 45 wherein the step of effecting a change of state from a fluent material to a solid comprises the steps of:

providing a plurality of resistive heating elements on said balloon surface;

applying an electric current to said resistive heating elements such that the elements heat the extruded stent material to an activation threshold sufficient to effect the phase transition to a solid.

47. A method according to claim 45 wherein the step of effecting a change of state to a solid comprises the steps of:

providing a balloon having a metallized porous surface;

applying radio frequency energy to said metallized surface to heat the extruded stent material to the activation threshold sufficient to effect the phase transition to a solid.

48. A method according to claim 45 wherein said step of effecting a change of state from a fluent material to a solid comprises the steps of:

providing an optical emitter in the balloon;

providing a fiber optic coupling to said optical emitter;

supplying through said fiber optic coupling a source of optical energy of sufficient intensity to effect photopolymerization of the fluent stent material.

49. A method according to claim 45 wherein said step of effecting a change of state to a solid comprises the steps of:

providing a balloon surface receptive to heating by the application of ultrasound energy;

applying a source of ultrasound energy to heat said balloon surface such that adjacent stent material is raised to its phase activation temperature and transitions to a solid state.

50. A method for forming a radiopaque bioresorbable stent in place in a blood vessel for repairing a stenosed or injured wall of the blood vessel comprising the steps of:

providing a balloon having a radiopaque microporous surface containing a quantity of fluent, radiopaque bioresorbable stent material capable of undergoing a phase transition from a fluent state to a solid state when a source of energy at a phase activation threshold is applied to the stent material;

introducing said balloon to a stenosed site within said blood vessel such that an annular space is formed between the wall of the blood vessel and the balloon surface;

increasing the pressure within said balloon such that the radiopaque fluent stent material is injected into said annular space;

applying a source of activation energy to said fluent material to effect said change of phase to a solid state;

removing the balloon from said blood vessel.

51. A method for creating a radiopaque stent in situ in a blood vessel, or the like having a substantially cylindrical vessel wall comprising:

providing a quantity of a radiopaque stent matrix material in a flowable form contained in a catheter balloon comprising a substantially cylindrical microporous membrane;

providing a fibrous bioresorbable filament material woven in a net-like structure about said microporous membrane;

advancing the catheter balloon along a path of travel within said blood vessel to a target site for medical intervention;

expanding the catheter balloon such that the bioresorbable filament material is advanced to the vessel wall;

extruding the flowable radiopaque stent matrix material through the microporous membrane to engulf the bioresorbable filament material;

applying a source of energy to solidify the flowable radiopaque matrix material such that the bioresorbable filament material is sealed in the solidified radiopaque matrix material;

removing the catheter balloon from said vessel.

52. A method according to claim 51 wherein said bioresorbable filament material comprises a suture-like thread comprising a radiopaque component, woven in a network structure and loosely adhered around said catheter balloon.

53. A method for treating an aneurysm or dissected site in a blood vessel characterized by a substantially cylindrical wall comprising:

providing a catheter balloon having a microporous membrane for containing a quantity of radiopaque stent matrix material in a fluent form;

providing a suture-like bioresorbable filler material woven in a loose net about said microporous membrane;

advancing said catheter balloon to a target site in said blood vessel;

expanding the catheter balloon to push the net of suture-like filler material against the cylindrical wall of said blood vessel;

extruding the radiopaque fluent stent material through the microporous membrane to engulf said net of suture-like material;

applying a source of energy to solidify said radiopaque fluent matrix material such that the thread-like suture material is sealed therein;

removing the microporous membrane from said blood vessels to provide a free passage for blood flow.

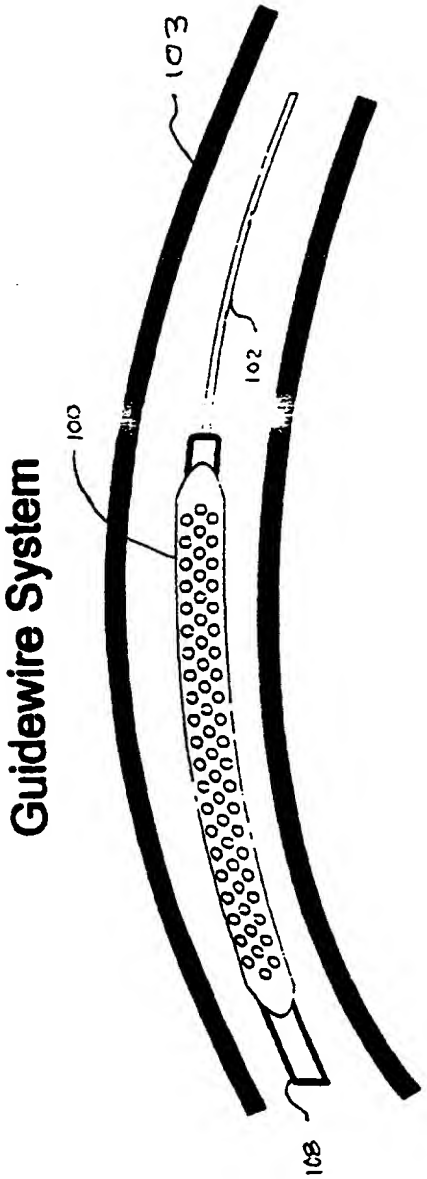

Guidewire System
103
102
100
108

FIG 1 A

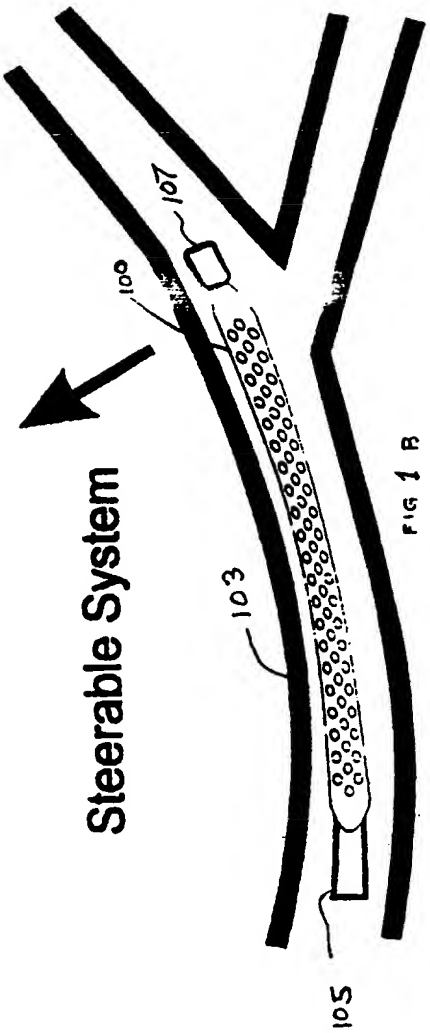

Steerable System
107
100
103
105

FIG 1 B

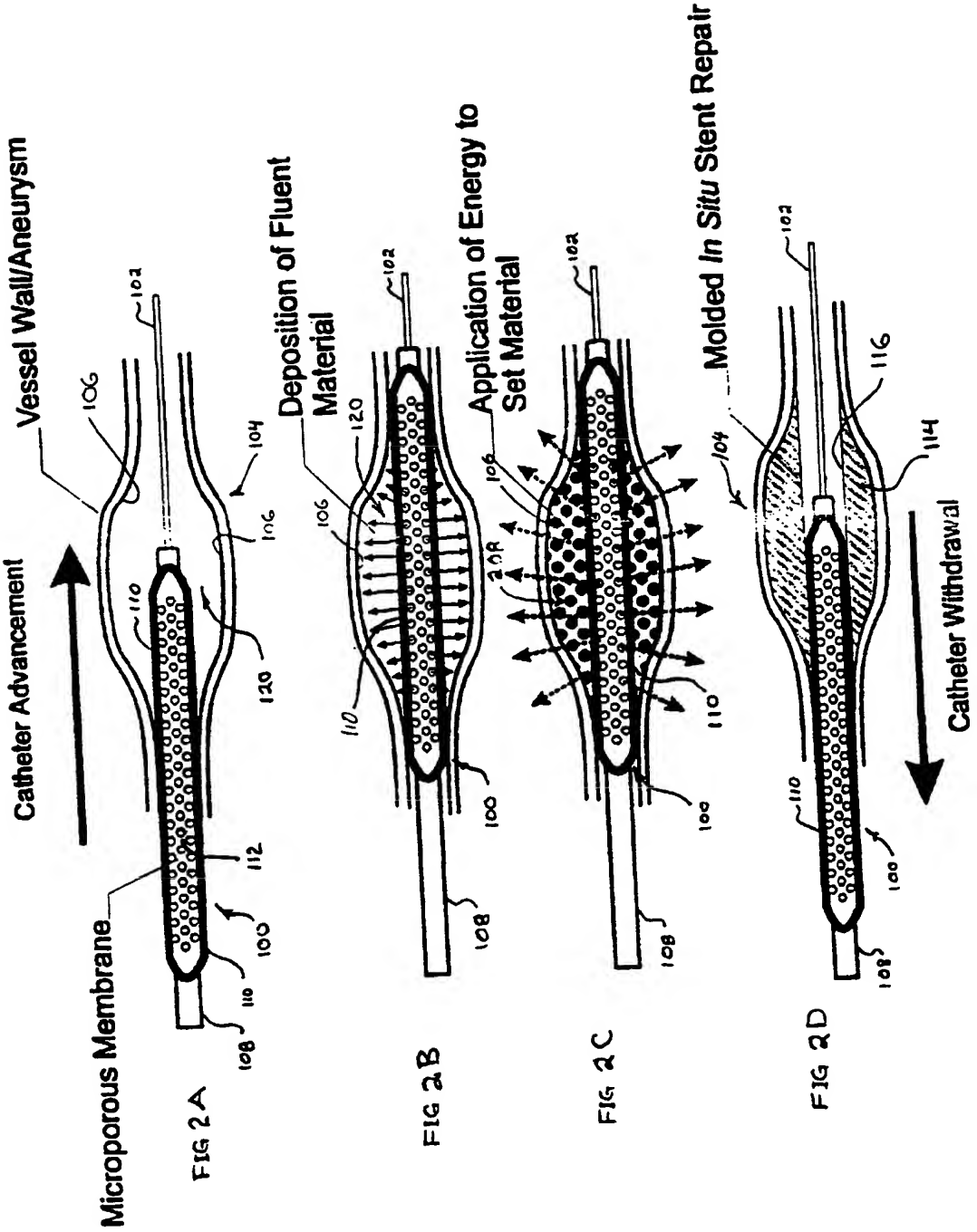


FIG 2A FIG 2B FIG 2C FIG 2D

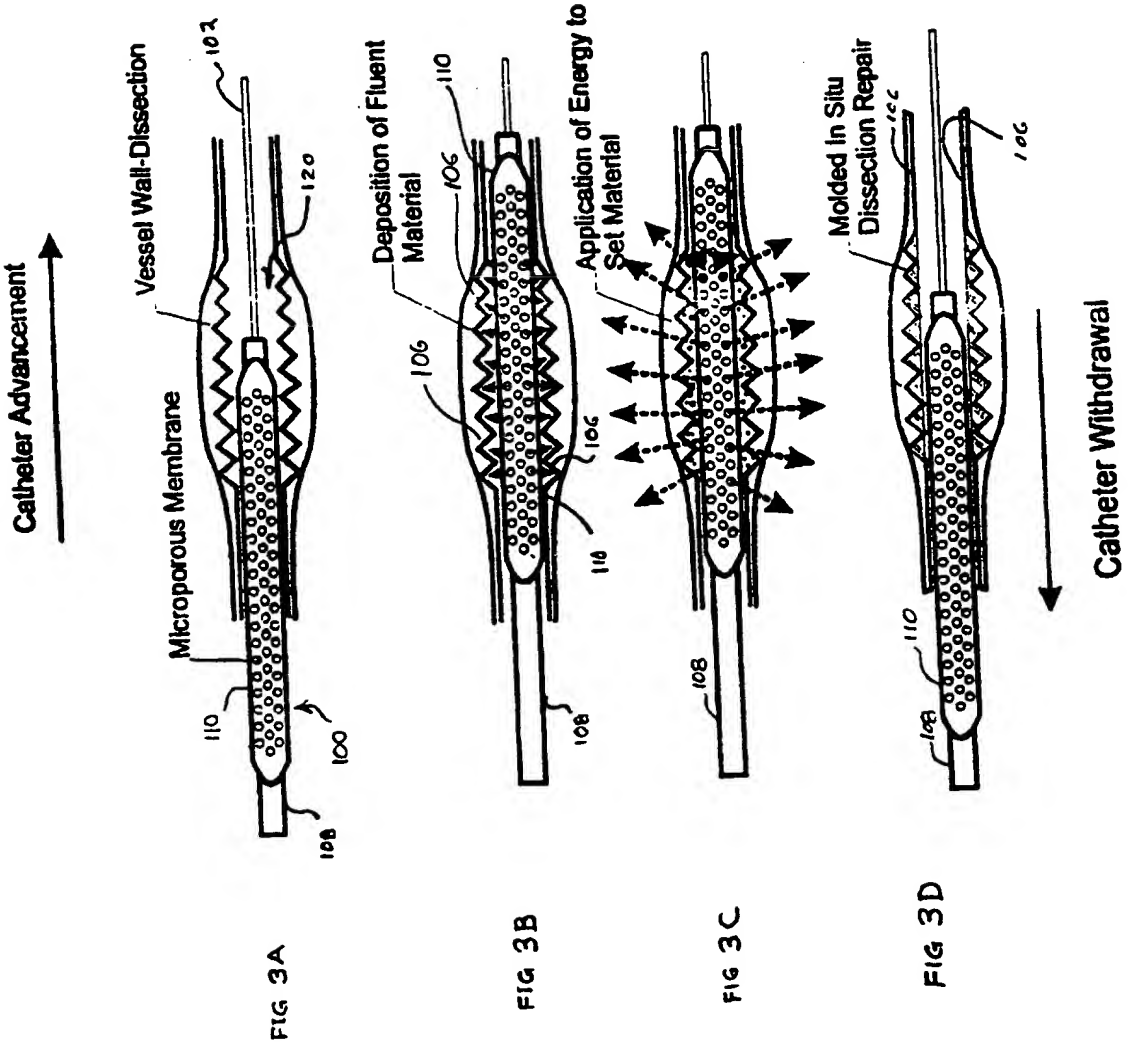


FIG 3A

FIG 3B

FIG 3C

FIG 3D

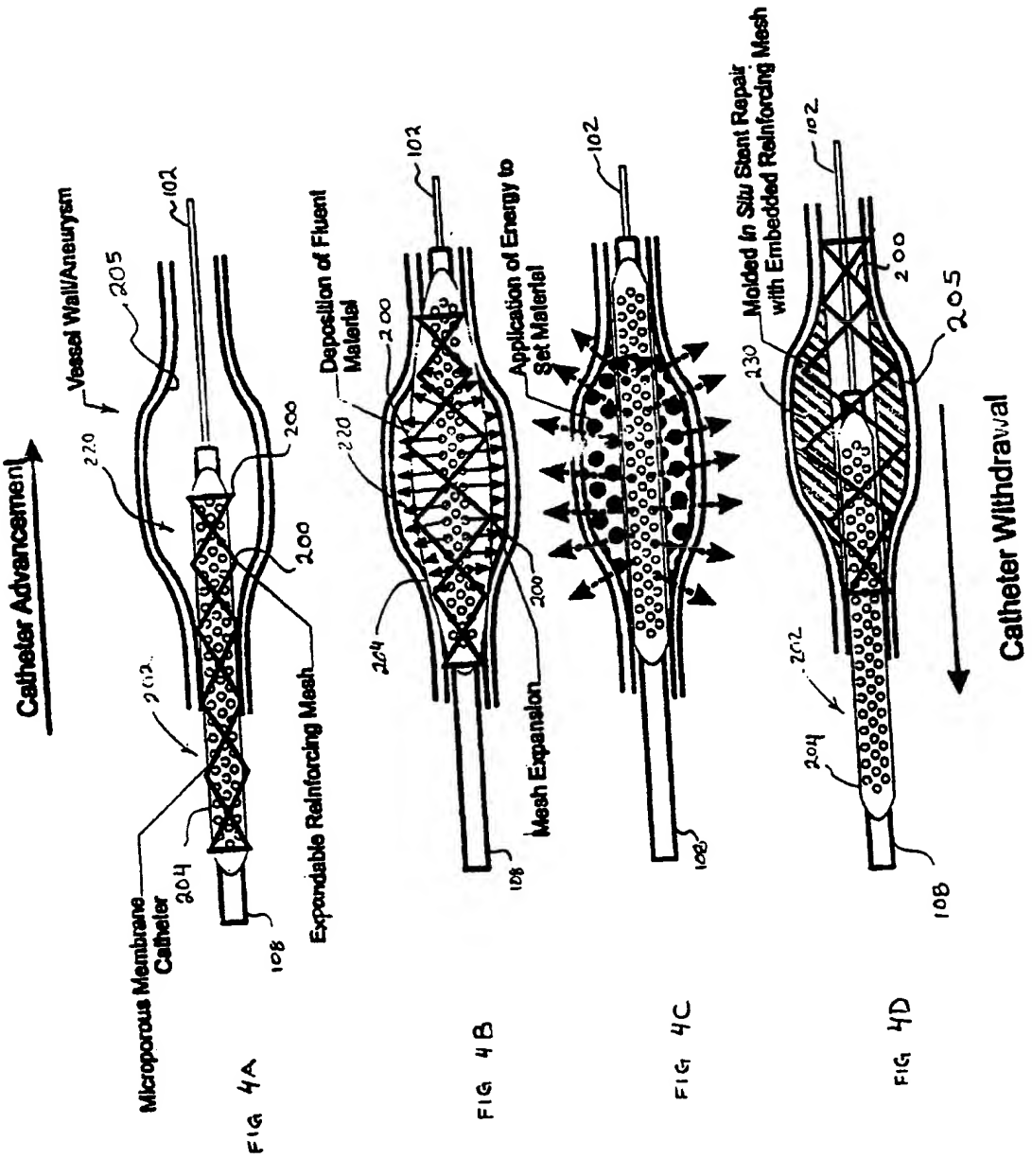
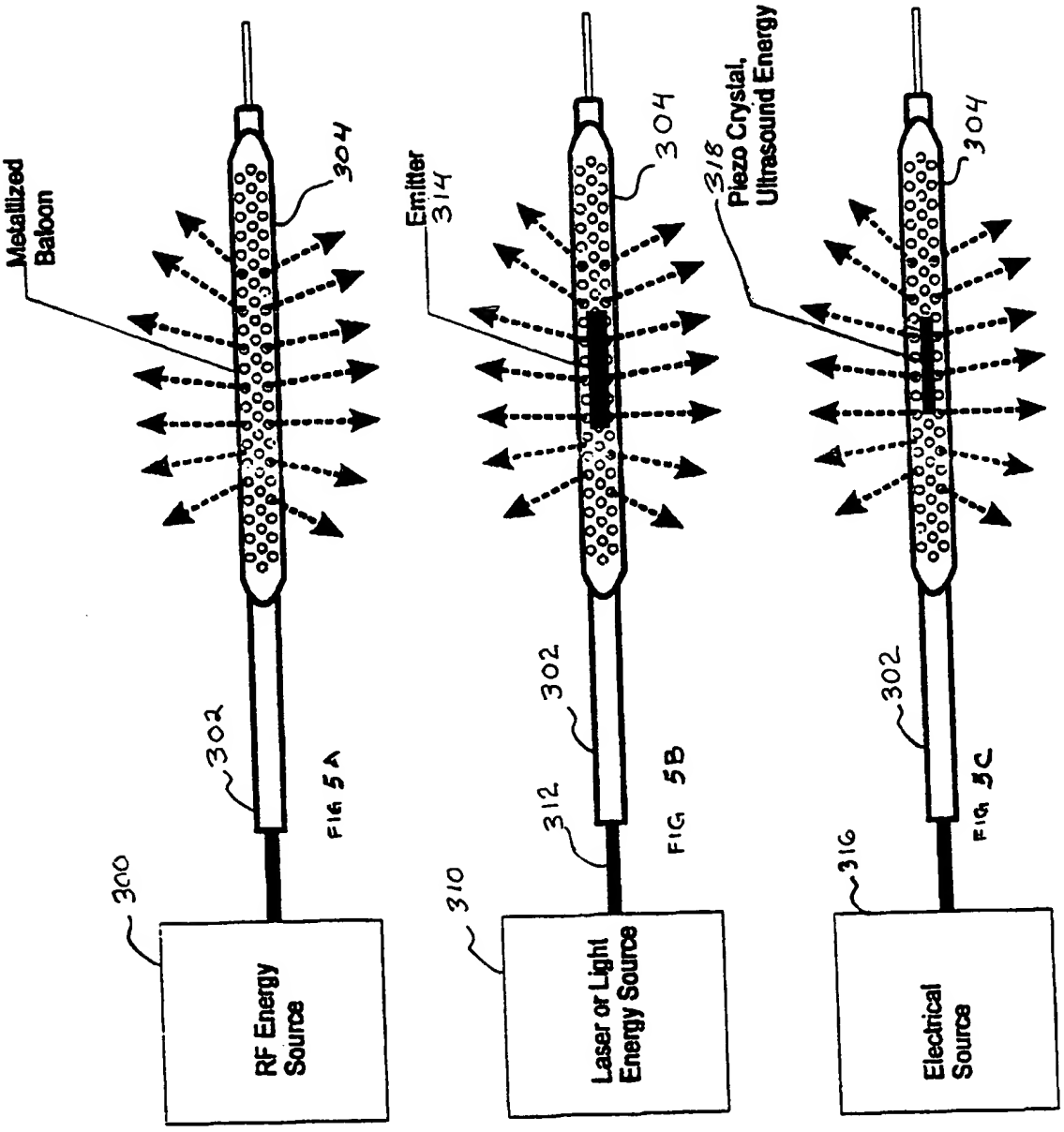


FIG 4A FIG 4B FIG 4C FIG 4D


Metallized Balloon
304
302
300
RF Energy Source
FIG 5A
Emitter 314
304
302
312
310
Laser or Light Energy Source
FIG 5B
318 Piezo Crystal, Ultrasound Energy
304
302
316
Electrical Source
FIG 5C

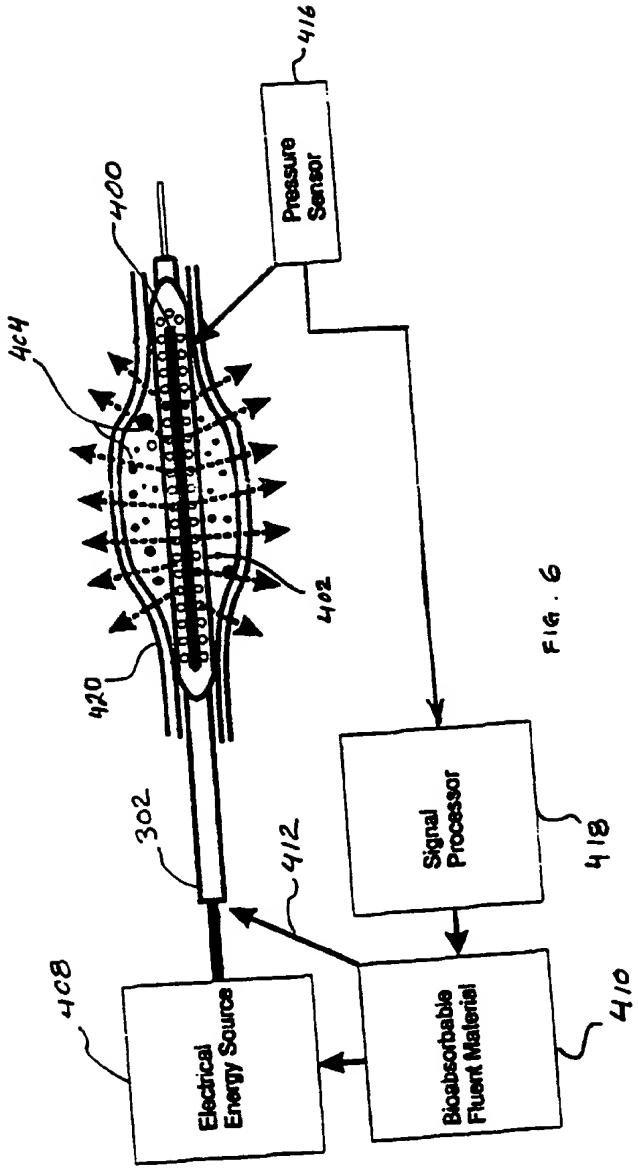

416
Pressure Sensor
400
404
402
420
302
412
Signal Processor
418
408
Electrical Energy Source
Bioabsorbable Fluent Material
410

FIG. 6

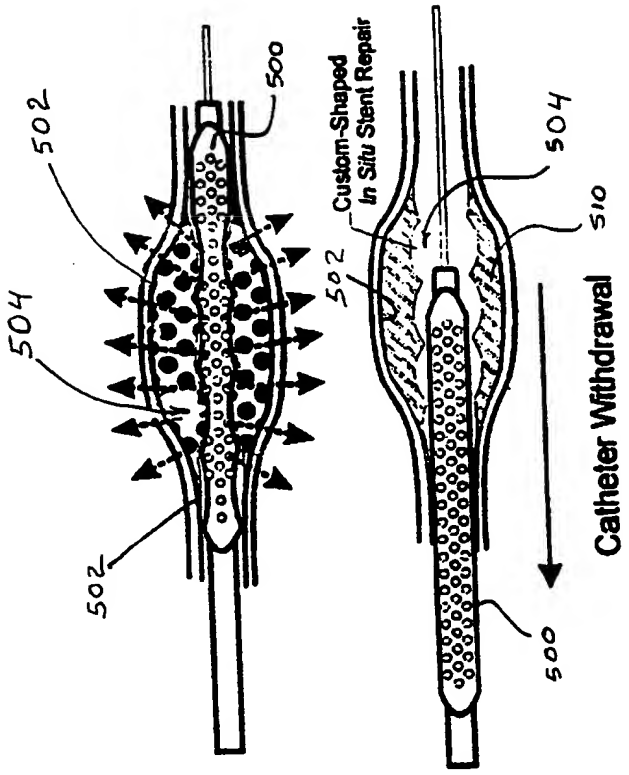

500
502
504
502
Custom-Shaped
In Situ Stent Repair
504
510
502
Catheter Withdrawal
500

FIG 7A

FIG 7B

INTERNATIONAL SEARCH REPORT

Internat. J Application No
PCT/US 98/04792

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06 A61L27/00 A61M29/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 591 199 A (PORTER CHRISTOPHER H ET AL) 7 January 1997 see column 4, line 1 - column 6, line 18; figures ---	1-4,7, 11-14,17
X	US 5 575 815 A (SLEPIAN MARVIN ET AL) 19 November 1996 see column 6, line 8 - line 19; figures see column 7, line 9 - column 8, line 18 ---	1,3,4,7, 11,13, 14,17
X	WO 95 08289 A (SCIMED LIFE SYSTEMS INC) 30 March 1995 see page 7, line 12 - page 8, line 11; figures	1-4,6,7
A	--- -/--	11-14, 16,17

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 July 1998	29. 07. 98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/US 98/04792

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 092 841 A (SPEARS JAMES R) 3 March 1992 see column 6, line 57 - column 9, line 49; claims 8-10; figures	1,3-5,7
A	-----	11, 13-15,17

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter. ational application No.
PCT/US 98/04792

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 8-10,18-53
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat J Application No
PCT/US 98/04792

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		WO 9117731 A	28-11-1991
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